IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

JAMES RODDEN, ISAAC MCLAUGHLIN, GABRIEL ESCOTO, MICHELLE RUTH MORTON, WADDIE BURT JONES, RYAN CHARLES BIGGERS, CAROLE LEANN MEZZACAPO, EDWARD BRYAN SURGEON, SUSAN REYNOLDS, ROY KENNETH EGBERT, and GEORGE GAMMON, on behalf of themselves and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	
DR. ANTHONY FAUCI, Chief COVID Response Director of the National Institute of Allergy and Infectious Diseases, JEFFREY ZIENTS, Coordinator of the COVID-19 Response, NATALIE QUILLIAN, Deputy COVID-19 Response Coordinator, DR. DAVID A. KESSLER, Chief Science Office of COVID Response, VICE ADMIRAL DR. VIVEK MURTHY, Surgeon General of the U.S., ABBE GLUCK, Special Counsel, EDUARDO CISNEROS, Director of Intergovernmental Affairs, BEN WAKANA, Director of Strategic Communications and Engagement, CLARKE HUMPHREY, Digital Director, DR. CYRUS SHAPAR, Data Director, DR. BECHARA CHOUCAIR, Vaccinations Coordinator, CAROLE JOHNSON, Testing Coordinator, TIM MANNING, Supply Coordinator, DR. ROCHELLE WALENSKY, Director of the Centers for Disease Control and Prevention, ROBIN	)	**CLASS ACTION COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** JURY TRIAL DEMANDED

CARNAHAN, Administrator of the U.S. General Services Administration, KIRAN AHUJA, Director U.S. Office of Personnel Management, DENIS MCDONOUGH, Secretary of Veterans Affairs, DEANNE CRISWELL, Director Federal Emergency Management Agency, L. ERIC PATTERSON, Director, Federal Protective Service, SHALANDA YOUNG, Acting Director of the Office of Management and Budget, JAMES M. MURRAY, Director U.S. SECRET SERVICE, WHITE HOUSE COVID-19 RESPONSE TEAM, SAFER FEDERAL WORKFORCE TASK FORCE, U.S. GENERAL SERVICES ADMINISTRATION, U.S. OFFICE OF PERSONNEL MANAGEMENT, DEPARTMENT OF VETERANS AFFAIRS, FEDERAL EMERGENCY MANAGEMENT AGENCY, FEDERAL PROTECTIVE SERVICE, OFFICE OF MANAGEMENT AND BUDGET, UNITED STATES SECRET SERVICE, and THE UNITED STATES OF AMERICA,	)
Defendants.	)

Plaintiffs and those similarly situated, by and through their attorneys at the New Civil Liberties Alliance ("NCLA"), hereby complain and allege the following:

INTRODUCTORY STATEMENT

a. By the spring of 2020, the novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, had spread across the globe. Since then, and because of the federal government's "Operation Warp Speed," three separate coronavirus vaccines have been developed and approved more swiftly than any other vaccines in our nation's history. The Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-

BioNTech COVID-19 Vaccine ("BioNTech Vaccine") on December 11, 2020.[1] Just one week later, FDA issued a second EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine").[2] FDA issued its most recent EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine") on February 27, 2021 (the only EUA for a single-shot vaccine).[3]

b. FDA fully approved the Pfizer Comirnaty Vaccine ("Comirnaty Vaccine") on August 23, 2021. Though both are affiliated with Pfizer, the BioNTech Vaccine and the Comirnaty Vaccines are legally distinguishable and on information and belief, the BioNTech and Comirnaty Vaccines are also factually distinguishable.

c. The EUA statute, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii), explicitly states that recipients of products approved for use under it be informed of the "option to accept or refuse administration," and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown."

d. On September 9, 2021, President Biden issued Executive Order 14,043 entitled "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees," *published as* 86 Fed. Reg. 50,989 (Sept. 14, 2021) ("EO 14,043"), proclaiming that "it is necessary to require COVID-19 vaccination for all Federal employees, subject to such exceptions as required by law."[4]

e. The Federal Work Force Task Force ("Task Force") was designated to serve as the intermediate enforcer of EO 14,043 (with the employing agencies subject to Task Force regulation

[1] *Pfizer-BioNTech Vaccine FAQ*, FDA, bit.ly/3i4Yb4e (last visited Oct. 29, 2021).

[2] *Moderna, About Our Vaccine*, bit.ly/2Vl4lUF (last visited Oct. 29, 2021).

[3] *EUA for Third COVID-19 Vaccine*, FDA, bit.ly/3xc4ebk (last visited Oct. 29, 2021).

[4] Henceforth in this Complaint, this Executive Order and the actions by federal agencies and agents of the federal government designed to enforce the Executive Order are collectively referred to as the "Federal Employee Vaccine Mandate."

being the ones left to directly interface with their employees). *See* 86 Fed. Reg. at 50,989 ("The Safer Federal Workforce Task Force (Task Force), established by Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing), has issued important guidance to protect the Federal workforce and individuals interacting with the Federal workforce.").

f. Specifically, since September 9, 2021, the Task Force has issued a *shifting set* of guidance instructions, published on the Task Force's website, designed to coerce federal workers into taking one of the EUA-approved vaccines ("Task Force Guidance"). *See* https://www.saferfederalworkforce.gov/ (last visited Oct. 29, 2021).[5] The Task Force Guidance contains a number of important features, but for present purposes the most critical is that it states, *in mandatory terms*, that "Federal employees need to be fully vaccinated *by November 22, 2021*." https://www.saferfederalworkforce.gov/faq/vaccinations/ (last visited Oct. 20, 2021) (emphasis added). However, the Task Force Guidance considers no one "fully vaccinated" until "2 weeks *after* they have received the requisite number of doses of a COVID-19 vaccine approved or authorized for emergency use …." *Id.* at Tab Vaccination Requirement for Federal Employees (New and Updated) (emphasis added).

[5] The guidance comes in the form of Frequently Asked Questions ("FAQs") organized in a series of webpage tabs that it is not possible to view all at one time—something that makes it difficult for federal workers to understand what is being required of them. *See* https://www.saferfederalworkforce.gov/faq/vaccinations/ (last visited Oct. 29, 2021). This problem is compounded because the FAQ page the Task Force has set up also includes various hyperlinks, so not only is the FAQ document chopped up into segmented tabs that cannot be viewed all at once, even if that were not the case, the FAQ document is not entirely self-contained. A regulatory pronouncement as important as the Federal Employee Vaccine Mandate should have been reduced to a single, self-contained document that is not constantly morphing into new forms via a living web document.

g. Thus, working backwards, this means that the Federal Employee Vaccine Mandate ordered by the President and carried out by the Task Force (and other federal agents) in reality establishes an imminent vaccination deadline of *November 8, 2021*. This is because the first dose of the two-dose Moderna COVID-19 vaccine needed to be taken by *October 11, 2021*, allowing the second dose to be received, with the appropriate gap between doses, on or before November 8, 2021. *Id.* And the first dose of the two-dose Pfizer BioNTech vaccine in turn needed to be received by *October 18, 2021*, so that recipients can get "the second dose [by] November 8, which is the deadline by which they need to have received both shots." *Id.* Finally, the one-dose regimen of the Johnson & Johnson vaccine also leaves "until *November 8* to receive that shot and still meet the November 22, 2021 deadline to be fully vaccinated." *Id.* (emphasis added).

h. Worse yet, federal employees *cannot even safely wait* until the last of those deadlines, *i.e.*, November 8, 2021, and assume that sufficient doses of the Johnson & Johnson vaccine will be available for them on that day. This is because the Task Force Guidance warns that meeting the deadlines rests exclusively on the shoulders of the employees, notwithstanding frequent shortages of a specific vaccine: "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." *Id.*

i. With two deadlines already having passed—one on October 11, 2021 (for the Moderna vaccine) and another on October 18, 2021 (for the Pfizer BioNTech vaccine), and where even the November 8, 2021 deadline to take the single-shot Johnson & Johnson vaccine looms, federal employees who object to this illegal Federal Employee Vaccine Mandate cannot await the issuance of regulations or agency-specific policies to come into compliance. Nor can they rely

upon a disciplinary grace period if they delay until November 8, 2021 to determine whether or not they can find a Johnson & Johnson vaccine within a reasonable distance of their home. Rather, they have been left with no viable option but to bring this class-action suit now and seek temporary and/or preliminary injunctive relief to block the Federal Employee Vaccine Mandate from continuing to operate pending the resolution of this litigation on the merits.

j. On information and belief, Plaintiffs aver that the Task Force and/or the White House COVID-19 Response Team have set these aggressive deadlines for compliance with the Federal Employee Vaccine Mandate knowing fully that they would precede the issuance of either regulations and other agency-specific policies precisely so as (a) to coerce federal employees into rushing to get a COVID-19 vaccine before such regulations or more detailed guidance providing true fair notice could be put in place; and (b) to frustrate the ability of federal employees wanting to seek judicial review to avoid taking a vaccine before they find themselves increasingly surrounded by more and more of their coworkers opting to acquiesce in the Federal Employee Vaccine Mandate.[6]

[6] A similar technique was employed when the Environmental Protection Agency issued its massive, energy-sector-restructuring Clean Power Plan in 2015, which the Supreme Court ultimately stayed, preventing it from taking effect. Indeed, Administrator Gina McCarthy had tempted that very outcome by bragging on Bill Maher's HBO television show that "however the Court ruled, most of the utilities are already in compliance, investments have been made, and we'll catch up," causing the *Wall St. Journal* to remark: "So much for the rule of law." *The EPA Deserves a Stay: The agency tries to run out the clock on its 'Clean Power' diktat*, WALL ST. J. (Oct. 29, 2015) (cleaned up). Approximately six years later, the Task Force is running the same play from Administrator McCarthy's 2015 playbook. And worse yet, unlike a capital investment in electricity-generating equipment, which can be unwound at least to some extent, taking a vaccine is truly irreversible. Just as in the Clean Power Plan situation, the *status quo* should be maintained to allow proper deliberation of the grave legal challenges presented here.

k. The Federal Employee Vaccine Mandate does not even exempt federal workers who are not reporting to the federal worksite, *i.e.*, those that are "on maximum telework or working remotely." *Id.*

l. Nor does the Federal Employee Vaccine Mandate recognize natural immunity. Exceptions to the mandate exist only "because of a disability or because of a sincerely held religious belief, practice, or observance." *Id.* at Tab Limited Exceptions to Vaccination Requirement (New). Natural immunity is not a "disability"; indeed, it is the *opposite* of a disability—it is instead a vital characteristic of the immune response that provides long-lasting protection from viral reinfection.

m. The lack of a remote work or a natural immunity exception, especially the latter, raises serious questions about whether the Federal Employee Vaccine Mandate is designed to accomplish a legitimate federal purpose. The paucity of exceptions on these very legitimate bases indicates that the Mandate is, at the very least, arbitrary and capricious in addition to being overbroad and poorly designed.

n. Also highlighting the arbitrary nature of the Mandate is the fact that compliance with the Federal Employee Vaccine Mandate can be achieved by receiving any vaccine "that has been listed for emergency use by the World Health Organization [WHO]," *id.* at Tab Vaccination Requirements for Federal Employees (New and Updated). Thus, the Federal Employee Vaccine Mandate can be satisfied by taking foreign vaccines that the FDA has *not approved in any fashion*, such as the Sinovac and Sinopharm Vaccines. No credible study has found that these foreign vaccines provide better or even equivalent protection than naturally acquired immunity.

o. Those who do not comply with the Federal Employee Vaccine Mandate by the aggressive deadlines discussed above face potential disciplinary action, *including termination of*

employment. *See id.* at Tab Enforcement of Vaccination Requirement for Employees (Updated) ("Employees covered by Executive Order 14043 who fail to comply with a requirement to be fully vaccinated or provide proof of vaccination and have neither received an exception nor have an exception request under consideration, are in violation of a lawful order. Employees who violate lawful orders are subject to discipline, up to and including termination or removal.").

p. Plaintiffs have all already contracted and fully recovered from COVID-19. As a result, they possess naturally acquired immunity, confirmed by recent SARS-CoV-2 antibody tests. Immunologist Dr. Hooman Noorchashm advises that it is *medically unnecessary* for these individuals to undergo a vaccination procedure at this point (which fact also renders the unnecessary procedure and any attendant risks medically unethical).

q. Yet, if the Plaintiffs elect not to take the vaccines, they face adverse disciplinary consequences. In short, the Federal Employee Vaccine Mandate is unmistakably coercive and cannot reasonably be considered anything other than an unlawful order. Furthermore, it represents an unconstitutional condition being applied to Plaintiffs' constitutional and statutory rights to bodily integrity and informed consent, respectively.

r. Plaintiffs, as named Class Representatives, bring this action on behalf of a class of similarly situated individuals—federal employees outside the uniformed services who have naturally acquired immunity to COVID-19 and who do not wish to take the vaccine, including, but not limited to, exercising their rights to decline medical treatment and/or to avoid potential side effects of the vaccines.

s. Given Plaintiffs' naturally acquired immunity, the Federal Defendants cannot establish a compelling governmental interest (or, in the alternative, even satisfy intermediate scrutiny) in overriding the constitutional rights and personal autonomy of Plaintiffs and those who

are similarly situated by essentially forcing them to be vaccinated by making their continued employment contingent upon their receiving a COVID-19 vaccine.

t. Naturally acquired immunity is at least as robust and durable as that attained through the most effective vaccines, and it is significantly more protective and long-lasting than some of the inferior foreign vaccines that the Task Force accepts. As a result, the Federal Employee Vaccine Mandate acts to nullify informed consent (since an informed federal worker may rationally opt to rely on natural immunity over vaccine-based immunity) and thus infringes upon Plaintiffs' rights, and the rights of those who are similarly situated, under the Fifth and Ninth Amendments to the United States Constitution.

u. The disciplinary action that the Task Force is using to leverage ostensibly voluntary compliance with its Federal Employee Vaccine Mandate is not proportional to the Task Force's purported public health aims. That renders the Federal Employee Vaccine Mandate an unlawful condition insufficiently germane to its purported purpose.

v. Even beyond its constitutional defects, the Task Force's unlawful Federal Employee Vaccine Mandate is irreconcilable with and frustrates the objectives of the federal statute governing administration of medical products authorized for emergency use only. That statute is the law of the land and it trumps mere Executive Orders and Task Force Guidance (or any other form of federal guidance for that matter).

w. Regardless of whether Pfizer recently received full FDA approval for the Comirnaty Vaccine, the remaining vaccines accepted by the Task Force have not and (as noted above) the Federal Employee Vaccine Mandate informs federal employees that all availability gaps fall on them, not on the federal officials setting the parameters of the mandate. As Pfizer itself acknowledges, the Comirnaty Vaccine is *not widely available* in the United States. And

despite its attempts to create equivalence between its BioNTech and Comirnaty Vaccines, the two are legally distinguishable (and, on information and belief, are factually distinguishable as well). Thus, even after the Comirnaty Vaccine's approval, the Federal Employee Vaccine Mandate still essentially forces individuals, including Plaintiff and those who are similarly situated, to take one of the EUA vaccines.

x. In sum, the Federal Employee Vaccine Mandate violates *both* the constitutional *and* federal statutory rights of Plaintiffs and those who are similarly situated because it undermines their bodily integrity and autonomy and conditions their employment on their willingness to take what for them and those working with them is a medically unnecessary vaccine. Accepting federal employment does not mean serving as a guinea pig for emergency use drugs. Forcing Plaintiff and others to take this vaccine will provide no discernible, let alone compelling, benefit either to Plaintiffs or to the federal employee community. Although obtaining the vaccine may raise Plaintiffs' antibody levels even higher, those levels are already equivalent to or greater than those of individuals who have received the most effective available vaccines, so any augmented benefit is negligible and cannot be the basis for such coercion. The unconstitutional conditions doctrine exists precisely to prevent government actors from clothing unconstitutional objectives and policies in the garb of supposed voluntarism when those actors fully intend and expect that the pressure they are exerting will lead to the targets of such disguised regulation succumbing to the government's will. Plaintiffs accordingly invoke this Court's Article III and inherent powers to insulate them from this pressure and to vindicate their constitutional and statutory rights.

PARTIES

1. Plaintiff James Rodden is an Assistant Chief Counsel at U.S. Immigration and Customs Enforcement, part of the Department of Homeland Security. He resides in Frisco, Texas and has worked for the federal government for 11 years.

2. Plaintiff Isaac McLaughlin, an electronics technician, is a civilian employee of the Department of the Navy. He resides in Robstown, Texas, which is located in the Southern District of Texas, and has worked for the federal government for 15 years.

3. Plaintiff Gabriel Escoto, an employee of U.S. Immigration and Customs Enforcement (ICE), resides in Midland, Texas.

4. Plaintiff Michelle Ruth Morton is an air traffic controller for the Federal Aviation Administration, part of the Department of Transportation. She resides in St. Cloud, Florida and has worked for the federal government for 14 years.

5. Plaintiff Waddie Burt Jones, is a resident of Georgia, and is a civilian employee of The U.S. Department of Agriculture.

6. Plaintiff Ryan Biggers is also a special agent with the Secret Service. He resides in Springfield, Virginia and has worked for the federal government for 18 years.

7. Plaintiff Carole LeAnn Mezzacapo is a resident of Louisianna, and a civilian employee of U.S. Immigration and Customs Enforcement, and works as an Enforcement and Removal Assistant. She has worked for the agency for 22 years.

8. Plaintiff Edward Surgeon is a District Veterinary Medical Specialist with the U.S. Department of Agriculture. He resides in Cumming, Georgia and has worked for the federal government for 25 years.

9. Plaintiff Dr. Susan Reynolds is a supervisor of food safety inspectors at the Department of Agriculture. She resides in Cumming, Georgia and has worked for the federal government for 10 years.

10. Plaintiff Roy Kenneth Egbert, II is a resident of Brick, New Jersey and works for the U.S. Immigration and Customs Enforcement.

11. Plaintiff George Gammon is a supervisory air marshal for the Transportation Security Administration, also part of the Department of Homeland Security. He resides in Palos Verdes, California and has worked for the federal government for 10 years.

12. Each of Plaintiffs is an "employee" within the meaning of 5 U.S.C. § 2105(a).

13. Defendant Dr. Anthony Fauci is the Task Force's Chief of the Covid Response and Director of the National Institute of Allergy and Infectious Diseases. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C., Bethesda, Maryland, and possibly other locations.

14. Defendant Jeffrey Zients is the Task Force's Coordinator of the COVID-19 Response. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

15. Defendant Natalie Quillian is the Task Force's Deputy COVID-19 Response Coordinator. She is also a member of the White House COVID-19 Response Team. She performs her official duties in Washington, D.C.

16. Defendant Dr. David A. Kessler is the Task Force's Chief Science Officer of COVID Response. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

17. Defendant Vice Admiral Dr. Vivek Murthy is on the Task Force and is the Surgeon General of the United States. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

18. Defendant Abbe Gluck is the Task Force's Special Counsel. She is also a member of the White House COVID-19 Response Team. She performs her official duties in Washington, D.C.

19. Defendant Eduardo Cisneros is the Task Force's Director of Intergovernmental Affairs. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

20. Defendant Ben Wakana is the Task Force's Director of Strategic Communications and Engagement. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

21. Defendant Clarke Humphrey is the Task Force's Digital Director. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

22. Defendant Dr. Cyrus Shapar is the Task Force's Data Director. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

23. Defendant Dr. Bechara Choucair is the Task Force's Vaccinations Coordinator. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

24. Defendant Carole Johnson is the Task Force's Testing Coordinator. She is also a member of the White House COVID-19 Response Team. She performs her official duties in Washington, D.C.

25. Defendant Tim Manning is the Task Force's Supply Coordinator. He is also a member of the White House COVID-19 Response Team. He performs his official duties in Washington, D.C.

26. Defendant Dr. Rochelle Walensky is Director of the Centers for Disease Control and Prevention. She is also a member of the White House COVID-19 Response Team. She performs her official duties in Atlanta, Georgia, Washington, D.C., and possibly other locations.

27. Defendant Robin Carnahan is Administrator of the United States General Services Administration, which is a member of the Task Force. She performs her official duties in Washington, D.C.

28. Defendant Kiran Ahuja is Director U.S. Office of Personnel Management, which is a member of the Task Force. She performs her official duties in Washington, D.C.

29. Defendant Denis McDonough is the Secretary of the Department of Veterans Affairs, which is a member of the Task Force. He performs his official duties in Washington, D.C.

30. Deanne Criswell is the Administrator of the Federal Emergency Management Agency ("FEMA"), which is a member of the Task Force. She performs her official duties in Washington, D.C.

31. L. Eric Patterson is Director of the Federal Protective Service, which is a member of the Task Force. He performs his official duties in Washington, D.C.

32. Shalanda Young is Acting Director of the Office of Management and Budget ("OMB"), which is a member of the Task Force. She performs her official duties in Washington, D.C.

33. James M. Murray is Director U.S. Secret Service, which is a member of the Task Force. He performs his official duties in Washington, D.C.

34. All of the preceding individual Defendants are named in their official capacity only.

35. Defendant the "White House Covid-19 Response Team" is an *ad hoc* assemblage of about 16 high-ranking federal officials put in place to set federal COVID-19 policy.[7] The White House Covid-19 Response Team is one of the three leaders of the Task Force. https://www.saferfederalworkforce.gov/ (last visited Oct. 29, 2021). It is principally located in Washington, D.C.

36. Defendant the Task Force (formally known as the "Safer Federal Workforce Task Force") is an *ad hoc* assembly of federal agencies and federal officials designed to set or implement COVID-19 policy. *Id.* It is principally located in Washington, D.C.

37. Defendant the United States General Services Administration is another of the three leaders of the Task Force. *Id.* It is principally located in Washington, D.C.

38. Defendant the United States Office of Personnel Management is the third and final leader of the Task Force. *Id.* It is principally located in Washington, D.C.

[7] For instance, the White House Covid-19 Response Team includes President Biden and Vice President Harris. Those officials have not been included as Defendants in this action, however, because it is sufficient that any relief entered in this case would run against the federal officials and agencies that *are* named in this Complaint, who or which, respectively, would then be prevented from enforcing an illegal Executive Order. *See, e.g., Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952) (holding President Truman's steel-seizure order, Executive Order 10,340, to be unconstitutional). The "Sawyer" in the case caption of *Youngstown* was Charles Sawyer, the Secretary of Commerce.

39. Defendant the Department of Veterans Affairs is a member of the Task Force. It is principally located in Washington, D.C.

40. Defendant FEMA is a member of the Task Force. It is principally located in Washington, D.C.

41. Defendant the Federal Protective Service is a member of the Task Force. It is principally located in Washington, D.C.

42. Defendant OMB is a member of the Task Force. It is principally located in Washington, D.C.

43. Defendant the United States Secret Service is a member of the Task Force. It is principally located in Washington, D.C.

44. Participant agencies in the Task Force have at least one office in the Southern District of Texas. Additionally, the agencies for which several of the named Plaintiff Class Representatives work are also located in this District, such as the Department of Agriculture (2801 Joe Fulton Rd.) and the Department of the Navy's Naval Air Station (800 North Shoreline Blvd.). Other large federal agencies also have offices in this Division and District including the Internal Revenue Service and the Social Security Administration (both at 1133 North Shoreline Blvd.), and the Department of Commerce's National Oceanic and Atmospheric Administration (426 Pinson Dr., N.W.).

45. The United States of America is the Government of the United States organized under the Constitution of the United States with service effected upon Merrick Garland the Attorney General of the United States, as well as the U.S. Attorney for the Northern District of Iowa.

STATUTORY AND NONSTATUTORY JURISDICTION AND VENUE

46. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1337, and 1361, as well as under so-called "nonstatutory" equitable jurisdiction[8] attaching to jurisdiction pursuant to Sections 1331, 1337, 1361 and/or 1651. That is because the claims here arise under the Constitution and statutes of the United States and because Plaintiffs seek prospective redress against federal actors in their official capacities to end the deprivation of Plaintiffs' federal rights and/or orders compelling Defendants to cease relying on an illegal Executive Order and instead to

[8] Before he became Justice Scalia, then-Associate Professor of Law Scalia helpfully defined the term "nonstatutory review" as follows:

> It has been noted that the phrase "nonstatutory review" is imprecise. All actions in federal courts are, strictly speaking, statutory. So-called "nonstatutory review" proceedings are, more accurately, those which are brought under *statutes of general applicability, as opposed to statutes specifically designed to enable judicial review of the actions of a particular agency or agencies*. For example, a common type of nonstatutory proceeding is the suit for injunction, brought under the "federal question" provision and the "all writs" provision of the Judicial Code, 28 U.S.C. §§ 1331, 1651 (1964)—provisions which may support suit against an official of any federal agency or indeed against private citizens. Such a nonstatutory proceeding may be contrasted with a "statutory review" proceeding under 15 U.S.C. § 45(c) (1964), a provision which sets forth in some detail the procedure for obtaining judicial review of a cease-and-desist order issued by the Federal Trade Commission.
>
> Thus, the provision of the Mandamus and Venue Act of 1962, 28 U.S.C. § 1361 (1964), giving district courts "original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff," does not remove such actions from the category of "nonstatutory review" proceedings. As so understood, the phrase, despite its imprecision, has distinct utility. *See* Fuchs, *Judicial Control of Administrative Agencies in Indiana*, 21 IND. L.J. 1, 11 (1952).

Antonin Scalia, *Sovereign Immunity and Nonstatutory Review of Federal Administrative Action: Some Conclusions from the Public-Lands Cases*, 68 MICH. L. REV. 867, 870 n.12 (1970) (paragraph break added) (emphasis added).

continue leaving the Plaintiff class unmolested in their rights as they existed prior to the issuance of Executive Order 14,043 on September 9, 2021.

47. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391. Plaintiff McLaughlin resides in this judicial district, and thus a substantial part of the events, actions, or omissions giving rise to the claim occurred in this judicial district, and several agencies that would carry out the Federal Employee Vaccine Mandate are located in this judicial district. Indeed, the Department of Veterans Affairs is one of the member agencies of the Task Force and it can be found in this District.

48. This Court's equitable powers permit it to issue "nonstatutory" injunctions to protect Plaintiffs against wayward government actors engaged in unconstitutional conduct. *See Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682 (1949) (no waiver of sovereign immunity is needed when federal officers "take action in the sovereign's name" that is "claimed to be unconstitutional," which is precisely what Plaintiffs here are claiming). *Id.* at 690. Therefore, as the Supreme Court had already "frequently … recognized" by the time it decided *Larson*, "a restraint may be obtained against the conduct of Government officials" without implicating sovereign immunity. *Id.* Because the President's Executive Order 14,043 is *ultra vires* and unconstitutional, Plaintiffs' claims fit within *Larson* and sovereign immunity does not shield the Order from review. The same is true of the Task Force Guidance and the Federal Employee Vaccine Mandate.

49. In addition, this Court may issue declaratory relief pursuant to 28 U.S.C. § 2201. "Further necessary or proper relief based on a declaratory judgment may [also] be granted …," including via injunction. *See Powell v. McCormack*, 395 U.S. 486, 499 (1969) ("A declaratory

judgment can then be used as a predicate to further relief, including an injunction. 28 U.S.C. § 2202 ….").

STATEMENT OF FACTS

I. BACKGROUND PERTAINING TO THE CORONAVIRUS PANDEMIC AND COVID-19 VACCINES

50. The novel coronavirus SARS-CoV-2, which can cause the disease COVID-19, is a contagious virus spread mainly from person to person, including through the air.

51. It is well settled that the coronavirus presents a significant risk primarily to individuals aged 70 or older and those with comorbidities such as obesity and diabetes. Bhattacharya and Kulldorff Joint Decl. ¶¶ 10-14 ("Joint Decl.") (Attachment A). *See* Smiriti Mallapaty, *The Coronavirus Is Most Deadly If You Are Older and Male*, NATURE (Aug. 28, 2020), *available at* https://www.nature.com/articles/d41586-020-02483-2 (last visited Oct. 29, 2021) (individuals 50 years or under face a negligible threat of a severe medical outcome from a coronavirus infection, akin to the types of risk that most people take in everyday life, such as driving a car).

52. In fact, a meta-analysis published by the WHO concluded that the survival rate for COVID-19 patients under 70 years of age was 99.95%. Joint Decl. ¶ 12.

53. CDC estimates that the survival rate for young adults between 20 and 49 is 99.95%, and for people ages 50-64 is 99.4%. Joint Decl. ¶ 12.

54. A seroprevalence study of COVID-19 in Geneva, Switzerland, reached a similar conclusion, estimating a survival rate of approximately 99.4% for patients between 50 and 64 years old, and 99.95% for patients between 20 and 49. Joint Decl. ¶ 13.

55. This past winter, FDA approved three vaccines pursuant to the federal EUA statute, 21 U.S.C. § 360bbb-3.

a. FDA issued an EUA for the BioNTech Vaccine on December 11, 2020.

b. Just one week later, FDA issued an EUA for the Moderna Vaccine.

c. FDA issued its most recent EUA, for the Janssen Vaccine, on February 27, 2021.

d. The Comirnaty Vaccine received full FDA approval on August 23, 2021.

56. In a letter to Pfizer, FDA states that "the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness." (emphasis added). FDA, "Letter to Pfizer, Inc." (October 29, 2021), *available at* https://www.fda.gov/media/150386/download (last visited Nov. 4, 2021).

a. The Comirnaty Vaccine is *not* widely available due to limited supply, as Pfizer also notes that "there is not sufficient approved vaccine [the Comirnaty] available for distribution to this population in its entirety at the time of the reissuance of this EUA." *See id.* at p. 9 fn. 7. *See also* FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Oct. 29, 2021).

b. Indeed, the Task Force Guidance governing the federal mandate warns that meeting the deadlines rests exclusively on the shoulders of the employees, availability problems being no excuse at that point: "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." *See* United States Government, "Safer Federal WorkForce," *available at* https://www.saferfederalworkforce.gov/faq/vaccinations/ (last visited Nov. 3, 2021).

57. Information regarding the differences between the BioNTech Vaccine and the Comirnaty Vaccine is not readily available. Generally speaking certain drugs that the public believes are identical, generic versions of brand name drugs for instance, do not need to be formulaically identical in actuality. FDA, "Generic Drugs: questions & Answers," *available at* https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q5 (last visited Nov. 4, 2021). Despite Pfizers' proclamations to the contrary, an analysis of the ingredients in the two indicates they are not, in fact, identical.The EUA status of the vaccines that are available at present in the United States means that FDA has not yet fully approved them but permits their conditional use nonetheless due to exigent circumstances.

58. The standard for EUA review and approval is lower than that required for full FDA approval.

59. Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control. *See* CDC, *Vaccine Testing and the Approval Process* (May 1, 2014), *available at* https://bit.ly/3rGkG2s (last visited Oct. 29, 2021).

60. The third phase generally takes place over years, because it can take that long for a new vaccine's side effects to manifest. *Id.*

61. The third phase must be followed by a period of regulatory review and approval, during which data and outcomes are peer-reviewed and evaluated by FDA. *Id.*

62. Finally, to achieve full approval, the manufacturer must demonstrate that it can produce the vaccine under conditions that assure adequate quality control.

63. FDA must then determine, based on "substantial evidence," that the medical product is effective and that the benefits outweigh its risks when used in accordance with the

product's approved labeling. *See* CDC, *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19* (Oct. 22, 2020), *available at* bit.ly/3x4vN6s (last visited Oct. 29, 2021).

64. In contrast to this rigorous, six-step approval process that includes long-term data review, FDA grants EUAs in emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic." FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), *available at* bit.ly/3x8wImn (last visited Oct. 29, 2021).

65. EUAs allow FDA to make a product available to the public based on the best available data, without waiting for all the evidence needed for full approval. *See id.*

66. The EUA statute lays out the: "Appropriate conditions designed to ensure that individuals to whom the product is administered are informed." This means they must be told:

> that the Secretary has authorized the emergency use of the product;
> of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
> of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

21 U.S.C. § 360bbb-3(e)(1)(A)(i).

67. Studies of immunizations outside of clinical-trial settings began in December 2020, following the first EUA for a COVID vaccine.

68. None of the precise EUA vaccines approved for use in the United States has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Indeed, trials conducted so far have *specifically excluded* survivors of previous COVID-19 infections. *See* Declaration of Dr. Hooman Noorchashm (Noorchashm Decl.) ¶ 28 (Attachment B).

69. Recent research indicates that vaccination presents a heightened risk of adverse side effects—including serious ones—to those who have previously contracted and recovered from COVID-19. Noorchashm Decl. ¶¶ 21-26; Joint Decl. ¶ 28; Oct. 18, 2021 Declaration of Jayanta Bhattacharya (Bhattacharya Decl.) ¶30 (Attachment D).

70. The heightened risk of adverse effects results from "preexisting immunity to SARS-Cov-2 [that] may trigger unexpectedly intense, albeit relatively rare, inflammatory and thrombotic reactions in previously immunized and predisposed individuals." Angeli *et al.*, *SARS-CoV-2 Vaccines: Lights and Shadows*, 88 EUR. J. INTERNAL MED. 1, 8 (2021).

II. PRIOR INFECTION LEADS TO NATURALLY ACQUIRED IMMUNITY TO COVID-19 AT LEAST AS ROBUST AS VACCINE-ACQUIRED IMMUNITY

71. Naturally acquired immunity developed after recovery from COVID-19 provides broad protection against severe disease from subsequent SARS-CoV-2 infection. Joint Decl. ¶¶ 15-24.

72. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 epidemic.[9] A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.[10] Bhattacharya Decl. ¶ 18.

[9] Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. *Nature*, *584*, 457-462. doi: 10.1038/s41586-020-2550-z

[10] Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, *455*, 532-536. doi: 10.1038/nature07231

73. Multiple extensive, peer-reviewed studies comparing naturally acquired and vaccine-acquired immunity have concluded overwhelmingly that the former provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (BioNTech and Moderna). Joint Decl. ¶¶ 18-23.

74. These studies confirm the efficacy of natural immunity against reinfection with COVID-19 and show that almost all reinfections are less severe than first-time infections and almost never require hospitalization. Joint Decl. ¶ 18-24.

75. A study from Israel found that vaccinated individuals had 13.1 times greater risk of testing positive, 27 times greater risk of symptomatic disease, and around 8.1 times greater risk of hospitalization than unvaccinated individuals with naturally acquired immunity. Joint Decl. ¶ 20.

76. The authors concluded that the "study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [BioNTech's research name] two-dose vaccine-induced immunity." Joint Decl. ¶ 20.

77. Recent Israeli data found that those who had received the BioNTech Vaccine were 6.72 times *more likely* to suffer a subsequent infection than those with natural immunity. David Rosenberg, *Natural Infection vs. Vaccination: Which Gives More Protection*? ISRAELNATIONALNEWS.COM (Jul. 13, 2021), *available at* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited Oct. 29, 2021).

78. Israeli data also indicates that the protection BioNTech grants against infection is short lived compared to natural immunity and degrades significantly faster. In fact, as of July 2021, vaccine recipients from January 2021 exhibited only 16% effectiveness against infection and 16% protection against symptomatic infection, increasing linearly until reaching a level of

75% for those vaccinated in April. *See* Nathan Jeffay, *Israeli, UK Data Offer Mixed Signals on Vaccine's Potency Against Delta Strain*, THE TIMES OF ISRAEL (July 22, 2021), *available at* bit.ly/3xg3uCg (last visited Oct. 29, 2021).

79. Those who received a second dose of the BioNTech Vaccine between January and April of this year were determined to have 39% protection against infection and 41% protection against symptomatic infection. The large number of breakthrough infections likely was the result of waning vaccine protection in the face of the Delta variant's spread. *See* Carl Zimmer, *Israeli Data Suggests Possible Waning in Effectiveness of Pfizer Vaccine*, THE NEW YORK TIMES (July 23, 2021), *available at* https://www.nytimes.com/2021/07/23/science/covid-vaccine-israel-pfizer.html (last visited Oct. 29, 2021); Kristen Monaco, *Pfizer Vax Efficacy Dips at 6 Months*, MEDPAGE TODAY (July 29, 2021), *available at* https://bit.ly/2VheBxw (last visited Oct. 29, 2021).

80. A CDC/IDSA clinician call on July 17, 2021, summarized the current state of the knowledge regarding the comparative efficacy of natural and vaccine immunity. The presentation reviewed three studies that directly compared the efficacy of prior infection versus mRNA vaccine treatment and concluded "the protective effect of prior infection was similar to 2 doses of a COVID-19 vaccine."

81. Given that there is currently *more* data on the durability of naturally acquired immunity than there is for vaccine immunity, researchers rely on the expected durability of naturally acquired immunity to predict that of vaccine immunity. Joint Decl. ¶ 23.

82. Indeed, naturally and vaccine-acquired immunity utilize the same basic immunological mechanism—stimulating the immune system to generate an antibody response. Joint Decl. ¶ 16.

83. The level of antibodies in the blood of those who have naturally acquired immunity was initially the benchmark in clinical trials for determining the efficacy of vaccines. Joint Decl. ¶ 16.

84. Studies have demonstrated prolonged natural immunity with respect to memory T and B cells, bone marrow plasma cells, spike-specific neutralizing antibodies, and IgG+ memory B cells following a COVID-19 infection. Joint Decl. ¶ 17.

85. New variants of COVID-19 resulting from the virus's mutation do not escape the natural immunity developed by prior infection from the original strain of the virus. Joint Decl. ¶¶ 29-33.

86. In fact, vaccine-acquired immunity only targets the spike-protein of the original Wuhan variant, whereas naturally acquired immunity recognizes the full complement of SARS-CoV-2 proteins and thus provides protection against a greater array of variants. Noorchashm Decl. ¶ 17.

87. While the CDC and the media have touted a study from Kentucky as proof that those with naturally acquired immunity should get vaccinated, that conclusion is unwarranted. As Drs. Bhattacharya and Kulldorff explain, although individuals with naturally acquired immunity who received a vaccine showed increased antibody levels, that does not translate into a clinical benefit. Put otherwise, "[t]his does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths" for those who already acquired natural immunity. Joint Decl. ¶ 37.

88. Furthermore, the study "did not address or attempt to quantify the magnitude of risk and adverse effects in its comparison groups." Noorchashm Decl. ¶¶ 29-31.

89. The Kentucky study is also problematic because it appears cherry-picked. In other words, the CDC gathered data on this subject from all 50 states, but seems to have chosen to draw attention only to the one state that yielded data that arguably supported its position. *See* Marty Makary, "Covid Confusion at the CDC," *The Wall Street Journal* (Sept. 13, 2021), *available at* https://www.wsj.com/articles/covid-19-coronavirus-breakthrough-vaccine-natural-immunity-cdc-fauci-biden-failure-11631548306 (last visited Nov. 3, 2021).

90. The CDC has also claimed that another study, of several thousand patients hospitalized with "covid-like illness," demonstrates the superiority of vaccine-achieved immunity. "Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19 Like Illness," *CDC* (Oct. 29, 2021), *available at* https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e1.htm (last visited Nov. 3, 2021).

91. This study is highly problematic for many reasons experts have pointed out, chief among them that its design meant that it did not actually address the question of whether the covid recovered benefit from being vaccinated. *See* Martin Kulldorff, "A Review and Autopsy of Two COVID Immunity Studies," *Brownstone Institute* (Nov. 2, 2021), *available at* https://brownstone.org/articles/a-review-and-autopsy-of-two-covid-immunity-studies/ (last visited Nov. 3, 2021).

92. Rather, "the CDC study answers neither the direct question of whether vaccination or Covid recovery is better at decreasing the risk of subsequent Covid disease, nor whether the vaccine rollout successfully reached the frail. Instead, it asks which of these two has the greater effect size. It answers whether vaccination nor Covid recovery is more related to Covid hospitalization or if it is more related to other respiratory type hospitalizations." *Id.*

93. Kulldorff explains that the Israeli study discussed above, indicating that naturally acquired immunity provides significantly better protection against reinfection, produced far more reliable results due to its design. *Id.*

94. Indeed, shortly after publishing the results of the study, the CDC (much more quietly) conceded that "A systematic review and meta-analysis including data from three vaccine efficacy trials and four observational studies from the US, Israel, and the United Kingdom, found no significant difference in the overall level of protection provided by infection as compared with protection provided by vaccination; this included studies from both prior to and during the period in which Delta was the predominant variant." "Science Brief: SARA-CoV-2 Infection-induced and Vaccine-induced Immunity," *CDC* (Oct. 29, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html (last visited Nov. 3, 2021).

95. In short, contrary to (some of) the claims of the CDC and the media, these studies do *not* establish a valid reason to mandate vaccination of individuals with naturally acquired immunity. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31.

96. The Janssen Vaccine provides immunity protection of somewhere between 66% and 85%, far below that conferred by natural immunity. Joint Decl. ¶ 16; Noorchashm Decl. ¶ 15.

97. The Chinese Sinovac Vaccine has been approved by WHO (making it adequate to satisfy the Task Force's policy), which itself determined that this vaccine prevented *symptomatic* disease in just 51% of those who received it. *See WHO Validates Sinovac COVID-19 Vaccine for Emergency Use and Issues Interim Policy Recommendations*, WHO.INT (June 1, 2021), *available at* bit.ly/3yitIW7 (last visited Oct. 28, 2021).

98. Other clinical studies have found that the Sinovac Vaccine offers even lower levels of protection against infection. For instance, a study of Brazilian healthcare workers determined a mere 50.39% efficacy in preventing infection. *See* Elizabeth de Faria et al., *Performance of Vaccination with Coronavac*[11] *in a Cohort of Healthcare Workers (HCW)—Preliminary Report*, MEDRXIV (Apr. 15, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.04.12.21255308v1 (last visited Oct. 29, 2021).

99. Real-world evidence also suggests that the Sinovac Vaccine provides only minimal protection against the Delta variant. *See* Alexander Smith, *China on 'High Alert' as Variant of Covid-19 Spreads to 5 Provinces*, NBCNEWS.COM (July 30, 2021), *available at* nbcnews.to/2VcK3NB (last visited Oct. 29, 2021); Chao Deng, *As Delta Variant Spreads, China Lacks Data on Its Covid-19 Vaccines*, WALL ST. J. (July 9, 2021), *available at* on.wsj.com/3rMjlXW (last visited Oct. 29, 2021); Matt D.T. Hitchings, et al., *Effectiveness of CoronaVac in the Setting of High SARS-Cov-2 P.1 Variant Transmission in Brazil: A Test-Negative Case-Control Study*, THE LANCET (July 25, 2021), *available at* bit.ly/3C6F41J (last visited Oct. 29, 2021).

100. The Sinopharm Vaccine, also from China, has likewise received WHO approval. Although its reported level of efficacy against symptomatic infection has been reported as reasonably high (78%), real-world experience has generated severe doubts about the accuracy of that estimate. Because of the Sinopharm Vaccine's poor performance, several countries have stopped using it. *See* Yaroslav Trofimov & Summer Said, Bahrain, *Facing a Covid Surge, Starts*

[11] Sinovac and Coronavac are the same. *See* WHO, *Who Validates Sinovac COVID-19 Vaccine For Emergency Use*, (June 1, 2021), *available at* https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations (last visited Oct. 29, 2021).

Giving Pfizer Boosters to Recipients of Chinese Vaccine, WALL ST. J. (June 2, 2021), *available at* on.wsj.com/3ljM0lX (last visited Oct. 29, 2021).

101. The COVISHIELD vaccine, manufactured by the Serum Institute of India and South Korea's SK Bioscience Co., Ltd., is also WHO-approved and thus recognized as adequate to satisfy the Federal Employee Vaccine Mandate. The WHO itself reported a mere 70.42% efficacy against *symptomatic* COVID-19 infection, which fell to 62.10% in individuals who received two standard doses. *See Recommendation on Emergency Use Listing on COVISHIELD Submitted by SIIPL*, WHO (Feb. 26, 2021), *available at* bit.ly/3rNjnPo (last visited Oct. 29, 2021); *Recommendation for an Emergency Use Listing of AZD1222 Submitted by AstraZeneca AB and Manufactured by SK Bioscience Co. Ltd*., WHO (Feb. 23, 2021), *available at* bit.ly/3yiQD3s (last visited Oct. 29, 2021).

102. None of these vaccines has been approved by the FDA for use in the United States.

103. Early data also suggests that naturally acquired immunity provides greater protection against both the Delta and Gamma variants than that achieved through vaccination. A recent analysis of an outbreak among a small group of mine workers in French Guiana found that 60% of fully vaccinated miners suffered breakthrough infections compared to *zero* among those with naturally acquired immunity. Nicolas Vignier, et al., *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinate Gold Miners, French Guiana, 2021*, 27(10) EMERG. INFECT. DIS. (Oct. 2021), *available at* https://wwwnc.cdc.gov/eid/article/27/10/21-1427_article (last visited Oct. 29, 2021).

104. In this vein, the CDC recently reported that "new scientific data" indicated that vaccinated people who experienced breakthrough infections carried similar viral loads to the unvaccinated (but not naturally immune), leading the CDC to infer that vaccinated people transmit

the virus at concerning levels. *See CDC Reversal on Indoor Masking Prompts Experts to Ask, "Where's the Data?"*, WASHINGTON POST (July 28, 2021), *available at* wapo.st/2THpmIQ (last visited Oct. 29, 2021). For example, 74% of cases in a Cape Cod outbreak occurred in vaccinated individuals, again demonstrating that the vaccines are inferior to natural immunity when it comes to preventing infection. *See* Molly Walker, *CDC Alarmed: 74% of Cases in Cape Cod Cluster Were Among the Vaxxed*, MEDPAGE TODAY (July 30, 2021), *available at* bit.ly/2V6X3UP (last visited Oct. 29, 2021).

105. As Drs. Bhattacharya and Kulldorff have explained, there is no legitimate public-health rationale for the Task Force to require proof of vaccination to participate in activities that do not involve care for high-risk individuals:

> Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero and natural immunity, which provides benefits that are at least as strong[.] At the same time, the requirement for … proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice.

Joint Decl. ¶¶ 50-51.

III. COVID-19 VACCINES CAN CAUSE SIDE EFFECTS, INCLUDING SEVERE ADVERSE REACTIONS

106. Though the COVID-19 vaccines appear to be relatively safe at a population level, like all medical interventions, they carry a risk of side effects. Those side effects include common, temporary reactions such as pain and swelling at the vaccination site, fatigue, headache, muscle

pain, fever, and nausea. More rarely, they can cause serious side effects that result in hospitalization or death. Joint Decl. ¶¶ 25-26.

107. The vaccines could cause other side effects that remain unknown at this time due to their relatively recent development. Joint Decl.¶¶ 26-27.

108. Put differently, as a matter of simple logic, one cannot be certain about the long-term effects of vaccines that have not been in existence for the long term and thus cannot have been studied over a span measured in years instead of months. For that reason, "[a]ctive investigation to check for safety problems is still ongoing." Joint Decl. ¶ 26.

IV. PLAINTIFFS HAVE ROBUST NATURALLY ACQUIRED IMMUNITY TO COVID-19

109. As noted above, Plaintiffs work at diverse geographical locations performing a variety of federal jobs, for instance, holding positions ranging from electronics technician to air traffic controller to Secret Service agent. Although nothing turns on their years of service, most of the named Class Representatives have spent more than a decade in federal service.

110. All Plaintiffs have contracted COVID-19, recovered, and have established, through recent serological testing, that they possess robust, naturally acquired immunity.

111. Some Plaintiffs have worked remotely and, in light of COVID-era vagaries in federal, state, and local policies, may do so again. Others are *still* working remotely.

112. Proofs of each Plaintiffs' natural immunity has been confirmed by Dr. Sam Pappas. Recent semi-quantitative antibodies screening test established that their levels of immune protection remain high. *See* Declaration of Dr. Sam Pappas (Pappas Decl.) ¶¶ 10-13 (Attachment C).

113. Dr. Noorchashm explains that substantial scientific literature demonstrates that, while the COVID-19 vaccines carry the possibility of side effects, as do all medical procedures,

the risk of harm is greater to those who have recovered from the disease. Noorchashm Decl. ¶¶12 -28.

114. Accordingly, mandating that Plaintiffs receive a COVID-19 vaccine violates fundamental tenets of medical ethics. Noorchashm Decl. ¶¶ 8-35.

115. Plaintiffs have real, substantial, and legitimate concerns about taking a COVID-19 vaccine in light of their natural immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves.

116. There are other federal employees who are similarly situated, e.g., they previously contracted COVID-19, they have naturally acquired immunity demonstrated by antibody testing, and they have real, substantial, and legitimate concerns about taking the COVID-19 vaccine in light of their naturally acquired immunity and the potential for short- and long-term side effects and potential adverse reactions from the vaccines themselves.

117. The Federal Employee Vaccine Mandate applies equally to employees working in government buildings or facilities as well as to those working remotely and thus Plaintiffs like those here who operate in a variety of different working arrangements can properly function as Class Representatives. *See also infra* at ¶¶ 133.

V. BACKGROUND AND THE TASK FORCE'S IMPOSITION OF A BLANKET FEDERAL EMPLOYEES VACCINE MANDATE

118. The Task Force was empowered by EO 14,043 to "issue[] important guidance to protect the Federal workforce and individuals interacting with the Federal workforce." 86 Fed. Reg. at 50,989.

119. The Task Force has put forth a shifting set of instructions, the Task Force Guidance, designed to coerce federal workers[12] into taking one of the EUA-approved vaccines. The Task Force Guidance has been published on the Task Force's website. https://www.saferfederalworkforce.gov/ (last visited Oct. 29, 2021).

120. The Task Force Guidance contains a number of important features. Most importantly, the Task Force Guidance proclaims, in mandatory terms, that "Federal employees *need to be* fully vaccinated by November 22, 2021." https://www.saferfederalworkforce.gov/faq/vaccinations/ (last visited Oct. 29, 2021) (emphasis added). In reality, however, federal employees must begin the vaccination process much earlier. This is because the Task Force Guidance considers no one "fully vaccinated" until "2 weeks after they have received the requisite number of doses of a COVID-19 vaccine approved or authorized for emergency use …." *Id*. at Tab Vaccination Requirement for Federal Employees (New and Updated) (emphasis added).

121. Thus, working backwards, this means that the Federal Employee Vaccine Mandate ordered by the President and carried out by the Task Force (and other federal agents) requires, in essence, that all federal employees be vaccinated by *November 8, 2021*.[13]

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[12] The Task Force Guidance applies to "employee[s]" as defined in 5 U.S.C. § 2105. https://www.saferfederalworkforce.gov/ at Tab Vaccination Requirement for Federal Employees (New and Updated) (last visited Oct. 29, 2021).

[13] The Task Force Guidance does provide that a "documented medical necessity" may lead to an extension grant to come into compliance even if the "employee does not meet the legal definition of 'disability' to be entitled to an accommodation under the Rehabilitation Act." Task Force Guidance at Tab Limited Exceptions to the Vaccination Requirement. The examples given in the Task Force Guidance, however, are quite limited: *i.e.*, a 90-day delay after receiving monoclonal antibodies or convalescent plasma for COVID-19 treatment. *See id.* They do not include natural immunity.

122. Worse yet, federal employees cannot safely wait until November 8, 2021 and assume that sufficient doses of the Johnson & Johnson vaccine will be available at that time. This is because the Task Force Guidance warns that meeting the deadlines rests exclusively on the shoulders of the employees, availability problems being no excuse at that point: "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." *Id.*[14]

123. With two intermediate deadlines already having passed on October 11, 2021 (for the first dose of the Moderna vaccine) and another having passed on October 18, 2021 (for the first dose of the Pfizer BioNTech vaccine), and even with the November 8, 2021 deadline to take the one-shot Johnson & Johnson vaccine looming, federal employees who do not wish to be subject to this illegal Federal Employee Vaccine Mandate cannot await the issuance of regulations or agency-specific policies to come into compliance. Rather, their only option is to proceed as they are doing here to bring this class action suit now seeking to obtain temporary and/or preliminary injunctive relief, as well as permanent injunctive relief to block the Federal Employee Vaccine Mandate from continuing to operate pending the resolution of this litigation on the merits.

124. On information and belief, Plaintiffs aver that the Task Force and/or the White House COVID-19 Response Team have set deadlines for compliance with the Federal Employee Vaccine Mandate that they knew would create a time crunch in order to rush as many federal

[14] The Federal Employee Vaccine Mandate does include a limited exception for the situation where an employee gets the first shot of a two-shot regimen, goes back for the second shot, and finds that the same vaccine is now unavailable, so that an employee is not forced to mix vaccines of different manufacturers. *See* Task Force Guidance at Tab Limited Exceptions to the Vaccination Requirement.

workers as possible into taking one of the COVID-19 vaccines. This compounds the legal errors of the mandate.

125. The Federal Employee Vaccine Mandate does not even exempt federal workers who are not reporting to the federal worksite, i.e., those that are "on maximum telework or working remotely." *Id.*

126. Nor does the Federal Employee Vaccine Mandate recognize naturally acquired immunity. Exceptions to the mandate exist only "because of a disability or because of a sincerely held religious belief, practice, or observance." *Id.* at Tab Limited Exceptions to Vaccination Requirement (New). Indeed, the Task Force Guidance specifically answers the question "Is an employee who has had a prior COVID-19 infection required to be fully vaccinated?" with the answer "Yes," as long as the person "has recovered from the acute illness (if the person had symptoms) and has satisfied the criteria to discontinue isolation." *Id.*

127. The lack of remote work and natural immunity exceptions, especially the latter, reveal that the Federal Employee Vaccine Mandate is not designed to effectuate a legitimate purpose, or show at the very least, it is arbitrary and capricious in its poor and overbroad design.

128. Increasing the arbitrary nature of the Mandate, the Task Force Guidance creates a balancing test applicable to granting "exceptions" that confers vast discretion on the implementing agencies: "Determining whether an exception is legally required will include consideration of factors *such as* [1] the basis for the claim; [2] the nature of the employee's job responsibilities; and [3] the reasonably foreseeable effects on the agency's operations, including [4] protecting other agency employees and the public from COVID-19. Because such assessments will be fact- and context-dependent, agencies are encouraged to consult their offices of general counsel with questions related to assessing and implementing any such requested accommodations." *See id.* at

Tab Limited Exceptions to Vaccination Requirement (New) (emphasis added). No federal employee will be able to determine what this means in advance, particularly because the "factors" are merely illustrative and lawyers at each agency's office of general counsel will need to be consulted to make the relevant determinations. Yet no relief from the mandate's aggressive deadlines is provided in the Task Force Guidance while uncertainty swirls about how this black box of exceptions will be administered.

129. Pregnancy does not qualify as a disability for purposes of the Task Force Guidance. *See id.*

130. Agencies are empowered by the Task Force Guidance to set a specific date by which they must seek an exemption (which would *inherently predate* November 8, 2021), even though they cannot know going in exactly what grounds will prove sufficient to prove a "disability" or a religion-based exemption. *See id.*

131. Employees must produce documentation to demonstrate that they are vaccinated to their agencies, even if such employees have previously attested to their vaccination status. *See id.* at Tab Vaccination Documentation and Information (New).

132. Additionally, compliance with the Federal Employee Vaccine Mandate can be attained by receiving any vaccine "that has been listed for emergency use by the World Health Organization [WHO]." *Id.* Thus, Federal Employee Vaccine Mandate can be met by taking foreign vaccines that the FDA has not approved in any fashion, such as the Sinovac, Sputnik, and Sinopharm Vaccines.

133. Harsh disciplinary action is threatened for those who do not comply with the aggressive deadlines. *See id.* at Tab Enforcement of Vaccination Requirement for Employees (Updated) ("Employees covered by Executive Order 14043 who fail to comply with a requirement

to be fully vaccinated or provide proof of vaccination and have neither received an exception nor have an exception request under consideration, are in violation of a lawful order. Employees who violate lawful orders are subject to discipline, up to and including termination or removal.").

134. More specifically, a regime of progressive discipline is established by the Task Force Guidance:

> [***Education and Counseling Phase, 5 days***] Consistent with the Administration's policy, agencies should initiate an enforcement process to work with employees to encourage their compliance. Accordingly, agencies should initiate the enforcement process with a brief period of education and counseling (5 days), including providing employees with information regarding the benefits of vaccination and ways to obtain the vaccine.
>
> [***Short Suspension, 14 days or less***] If the employee does not demonstrate progress toward becoming fully vaccinated through completion of a required vaccination dose or provision of required documentation by the end of the counseling and education period, it should be followed by a short suspension (14 days or less).
>
> [***Removal***] Continued noncompliance during the suspension can be followed by proposing removal.
>
> [***Operational Exceptions***] Unique operational needs of agencies and the circumstances affecting a particular employee may warrant departure from these guidelines if necessary, but consistency across government in enforcement of this government-wide vaccine policy is desired, and the Executive Order does not permit exceptions from the vaccination requirement except as required by law.

Id. at Tab Enforcement of Vaccination Requirement for Employees (Updated) (paragraph breaks added).

135. Enforcement can begin as soon as November 9, 2021, meaning (coupled with 5- and 14-day periods noted above) that by as soon as *November 28, 2021*, the Federal Employees Vaccine Mandate could result in termination.[15] *Id.* And by the earlier date of *November 14, 2021*,

[15] The Task Force Guidance provides that collective bargaining or other agency processes could delay this timeline. *See* Task Force Guidance at Tab Enforcement of Vaccination Requirement for Employees (Updated).

noncompliant federal employees could face the start of suspension periods, which would also inflict injury on such federal employees.

136. It is also important to note that a different part of the Task Force Guidance specifically indicates that collective bargaining rights against the Federal Employees Vaccine Mandate are restricted: "[B]argaining over this Government-wide policy will be *limited to impact and implementation issues* not otherwise addressed in the guidance. Moreover, agencies must implement Government-wide policy by the deadline, so any bargaining that has not been completed by the time implementation must begin will have to be finished post-implementation." *Id.* at Tab Labor Relations Related to Vaccination.

137. And, of course, potential litigation by those not wishing to be vaccinated was a prospect that was or should have been reasonably foreseeable to the Defendants.

VI. PLAINTIFFS HAVE EXPERIENCED, AND WILL CONTINUE TO EXPERIENCE, CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF THE FEDERAL EMPLOYEE VACCINE MANDATE

138. Plaintiffs either must receive a COVID-19 vaccine or face disciplinary action, including loss of employment. Accordingly, Plaintiffs' personal autonomy and livelihoods are being infringed.

139. By threatening adverse professional and personal consequences, the Federal Employee Vaccine Mandate not only directly and palpably harms Plaintiffs' bodily autonomy and dignity, but it forces them to endure the stress and anxiety of choosing between their employment—upon which they and their families rely—and their health.

140. The risk-avoidance benefits that the Task Force Guidance implementation provides, compared to the restrictions and intrusive options offered to Plaintiffs, are disproportionate. Similarly, given that naturally acquired immunity confers equal or greater

protection than that provided by the vaccines (especially with respect to some of the WHO-approved vaccines that Defendants consider adequate to fulfill the Federal Employee Vaccine Mandate's requirements), that mandate is arbitrary and irrational. There is no indication that the Federal Employee Vaccine Mandate is tailored to account for its impact on those who have acquired natural immunity. In fact, official explanations of this mandate specifically refuse to recognize those with natural immunity as posing different issues and requiring different treatment as compared to unvaccinated individuals who lack natural immunity.

CLASS ACTION ALLEGATIONS

141. ***Class Definition.*** Plaintiffs brings this action on behalf of themselves and all others similarly situated ("the Class"), pursuant to Federal Rule of Civil Procedure 23. The Class is defined as follows:

> (i) All non-uniformed service federal employees within the meaning of 5 U.S.C. § 2105 employed by the United States government (ii) on or after October 8, 2021 (the deadline for the earliest of those employees to become vaccinated against COVID-19), including employees newly hired, whether or not they work at federal buildings or other facilities, at home, or both (iii) who have naturally acquired immunity demonstrable by antibody testing and where (iv) such employees have withheld their consent to taking such a vaccine.

142. For purposes of this Complaint and because this suit is being brought as a class action, references to Plaintiffs should be construed not just as applying to the named Class Representatives but as applying to all Class Members even where not explicitly stated.

143. ***Numerosity.*** The exact size of the class is unknown. However, there are at least 45 million covid recovered individuals in the United States. Martin Kulldorff and Jay Bhattacharya, "How Fauci Fooled American," *Newsweek* (Nov. 1, 2021). According to the Office of Personnel Management ("OPM"), there are 2.1 million federal civilian workers. *See* Congressional Research Service, *Federal Workforce Statistics Sources: OPM and OMB* at 1 (June

24, 2021), *available at* https://sgp.fas.org/crs/misc/R43590.pdf (last visited Oct. 29, 2021). One-fifth to four-tenths of 2.1 million federal workers equals a minimum of about 400,000 such workers, leaving tens of thousands of potential Class Members even if the desire to take a COVID-19 vaccine runs at about 90% among federal workers with natural immunity. Hence, the numerosity requirement in Fed. R. Civ. P. 23(a)(1) is readily met here.

144. ***Commonality.*** There are multiple questions of law and fact common to the Class, including but not limited to:

a. Whether the Federal Employee Vaccine Mandate constitutes an unconstitutional infringement on Plaintiffs' rights to bodily autonomy and to decline medical treatment under the Fifth and Ninth Amendments to the United States Constitution;

b. Whether the Federal Employee Vaccine Mandate creates an unconstitutional condition that impedes the exercise of Plaintiffs' constitutionally protected rights;

c. Whether the Federal Employee Vaccine Mandate violates Plaintiffs' equal protection rights;

d. Whether the Federal Employee Vaccine Mandate violates Plaintiffs' federal statutory rights under the Emergency Use Authorization (EUA) statute; and

e. Whether the Federal Employee Vaccine Mandate Plaintiffs' is arbitrary and capricious with respect to Plaintiffs.

As a result, the commonality requirement of Fed. R. Civ. P. 23(a)(2) is met here.

145. ***Typicality.*** Plaintiffs' claims are typical of the Class, as they have naturally acquired immunity to COVID-19, as verified by recent antibody tests, they are federal employees,

and they object to the Federal Employee Vaccine Mandate on the grounds that it violates their constitutional and statutory rights as described above. As a result, the typicality requirement of Fed. R. Civ. P. 23(a)(3) is met here.

146. ***Adequacy of Representation.*** Plaintiffs will fairly and adequately protect the interests of the Class Members. Plaintiffs' interests are aligned with, and not antagonistic to, those of the other members of the Class. Additionally, Plaintiffs are seeking identical declaratory and injunctive relief that would benefit all putative Class Members. Plaintiffs have also retained counsel competent and experienced in the prosecution of class-action litigation to represent themselves and the Class. As a result, the adequacy-of-representation requirement of Fed. R. Civ. P. 23(a)(4) is met here.

147. ***Fed. R. Civ. P. 23(b)(2) Class Type.*** Certification for injunctive and declaratory relief is appropriate under Rule 23(b)(2) because Defendants have both acted (principally by mandating that federal employees receive the vaccines) and declined to act (via their refusal to recognize natural immunity) on grounds that generally apply to the whole class. This also makes temporary, preliminary, and permanent injunctive relief appropriate "respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

148. ***Class Action Superiority & Efficiency.*** Additionally, though it is not necessary to plead as part of a Rule 23(b)(2) class action, class-wide treatment of the common issues presented by this suit against Defendants in a single forum represents a superior means of determining Defendants' liability to each Class Member than potentially hundreds or thousands (or even more) of individual lawsuits. As a result, class-wide adjudication of Defendants' liability followed by the grant of undifferentiated declaratory and injunctive relief is the most efficient means of adjudication. Judicial clarification that the Federal Employees Vaccine Mandate is

unlawful in the near term would also provide significant efficiencies to the federal Defendants (and the United States' fisc), avoiding the need to pay for expensive backpay remedies and avoiding the reintegration of a federal worker later ordered to be reinstated to his or her job.

CLAIMS FOR RELIEF

COUNT I: VIOLATION OF THE RIGHT TO REFUSE UNWANTED AND MEDICALLY UNNECESSARY CARE

149. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

150. The Federal Vaccine Mandate requires Plaintiffs to take a vaccine without their consent—and against the medical advice of experts—thereby depriving them of their ability to refuse unwanted medical care.

151. The Supreme Court has recognized that the Ninth and Fourteenth Amendments protect an individual's right to privacy. A "forcible injection … into a nonconsenting person's body represents a substantial interference with that person's liberty[.]" *Washington v. Harper*, 494 U.S. 210, 229 (1990). The common law baseline is also a relevant touchstone out of which grew the relevant constitutional law. *See, e.g., Cruzan v. Dir., Mo. Dep't of Public Health*, 497 U.S. 261, 278 (1990) ("'At common law, even the touching of one person by another without consent and without legal justification was a battery'"). *See* W. Keeton, D. Dobbs, R. Keeton, & D. Owen, PROSSER AND KEETON ON LAW OF TORTS § 9, pp. 39-42 (5th ed. 1984).); *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129-130, 105 N.E. 92, 93 (1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.").

152. The Fifth Amendment's Due Process Clause is applicable here, not the Fourteenth Amendment's Due Process Clause (which applies only to the States). But the same substantive due process right to privacy is protected by Fifth Amendment due process of law. *See Webster v. Doe*, 486 U.S. 592, 601-02 (1988) (CIA employee was permitted to advance claims, *inter alia*, that he was being deprived of his constitutional rights to privacy under the Fifth Amendment even though he possessed no right of judicial review under the Administrative Procedure Act to contest his discharge).

153. Subsequent Supreme Court decisions have made explicit that the Constitution protects a person's right to "refus[e] unwanted medical care." *Cruzan*, 497 U.S. at 278; *King v. Rubenstein*, 825 F.3d 206, 222 (4th Cir. 2016) (recognizing same).

154. This right is "so rooted in our history, tradition, and practice as to require special protection under the Fourteenth Amendment." *Washington v. Glucksberg*, 521 U.S. 702, 722 n.17 (1997). Again, as noted above in paragraph 144, there is no reason to confine that conclusion to cases involving the Fourteenth Amendment's Due Process Clause rather than applying that conclusion to the Fifth Amendment's Due Process Clause as well.

155. The Court has explained that the right to refuse medical care derives from the "well-established, traditional rights to bodily integrity and freedom from unwanted touching." *Vacco v. Quill*, 521 U.S. 793, 807 (1997).

156. The Ninth Amendment similarly protects the rights to privacy and bodily integrity. *See Griswold v. Connecticut*, 381 U.S. 479, 488 (1965) (Goldberg, J., concurring) ("The language and history of the Ninth Amendment reveal that the Framers of the Constitution believed that there are additional fundamental rights, protected from governmental infringement, which exist

alongside those fundamental rights specifically mentioned in the first eight constitutional amendments.").

157. Coercing employees to receive a vaccine (whether approved under an EUA or fully by the FDA) for a virus that presents a near-zero risk of illness or death to them and which they are exceedingly unlikely to pass on to others because those employees already possess natural immunities to the virus, violates the liberty and privacy interests that the Fifth and Ninth Amendments protect.

158. "Government actions that burden the exercise of those fundamental rights or liberty interests [life, liberty, property] are subject to strict scrutiny, and will be upheld only when they are narrowly tailored to a compelling governmental interest." *Does v. Munoz*, 507 F.3d 961, 964 (2007).

159. Defendants cannot show that they have a compelling interest in coercing Plaintiffs or others similarly situated into taking a COVID-19 vaccine, because Defendants have no compelling interest in treating employees with naturally acquired immunity any differently from employees who obtained immunity from a vaccine. Nor, in light of the Task Force Guidance's arbitrariness and evidentiary defects, could the Federal Employee Vaccine Mandate satisfy intermediate scrutiny.

160. All Defendants say to justify refusing to provide an exception for natural immunity to the Federal Employee Vaccine Mandate is this:

> NEW **Q: Is an employee who has had a prior COVID-19 infection required to be fully vaccinated?**
>
> A: Yes, an employee who has had a prior COVID-19 infection is required to be fully vaccinated. The CDC recommends that vaccination of people with known current SARS-CoV-2 infection should be delayed until the

> person has recovered from the acute illness (if the person had symptoms) and has satisfied the criteria[16] to discontinue isolation.

161. This simple question-and-answer on the Task Force's FAQ page dodges the scientific issues concerning naturally acquired immunity as compared to vaccine-based immunity. And as a result, this simple and singular FAQ answer cannot overcome the vast amount of scientific literature that Plaintiffs can cite and have cited to establish otherwise. Furthermore, as Drs. Bhattacharya, Kulldorff, and Noorchashm attest, the study from Kentucky that the CDC has elsewhere touted has been both wrongly interpreted and incorrectly portrayed by the media. *See* Joint Decl. ¶ 37; Noorchashm Decl. ¶¶ 29-31.

162. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. Noorchashm Decl. ¶¶ 14-17; Joint Decl. at ¶¶ 15-24; Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination in Previously Infected Individuals*, MEDRXIV (June 5th, 2021), *available at* https://bit.ly/2TFBGcA (last visited Oct. 29, 2021); *see also* Yair Goldberg, et al., *Protection of Previous SARS-Cov-2 Infection Is Similar to That of BNT162b2 Vaccine Protection: A Three-Month Nationwide Experience from Israel*, MEDRXIV (Apr. 20, 2021), *available at* https://bit.ly/3zMV2fb (last visited Oct. 26, 2021); Michael Smerconish, *Should Covid Survivors and the Vaccinated Be Treated the Same?*: CNN Interview with Jay Bhattacharya, Professor of Medicine at Stanford University (June 12, 2021), *available at* https://cnn.it/2WDurDn (last visited

[16] This word is hyperlinked in the FAQ to a CDC document but that document addresses only the physical isolation (*i.e.*, quarantine) and precautions to be followed as to people with COVID-19. Accordingly, the hyperlinked document does not address the issue of natural immunity at all. *See Ending Isolation and Precautions for People with COVID-19: Interim Guidance* (updated Sept. 14, 2021), *available at* https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html (last visited Oct. 29, 2021).

Oct. 29, 2021); Marty Makary, *The Power of Natural Immunity*, WALL STREET JOURNAL (June 8, 2021), *available at* https://on.wsj.com/3yeu1Rx (last visited Oct. 29, 2021).

163. In recognition of the highly protective character of natural immunity, the European Union has recognized "a record of previous infection" as a substitute for any vaccine passport requirements. Noorchashm Decl. ¶ 38. Even France's controversial and very restrictive mandate on the ability to participate in daily life focuses on a person's immunity rather than their vaccine status—treating natural immunity and vaccine immunity equally. *See, e.g.*, Clea Callcutt, *France Forced to Soften Rules After Coronavirus Green Pass Backlash*, POLITICO (July 20, 2021), *available at* https://politi.co/3f9AZzS (last visited Oct. 29, 2021).

164. Similarly, the United States requires everyone, including its citizens, to provide proof of a negative COVID-19 test before returning to the country from abroad. Yet, documentation of recovery suffices as a substitute, although proof of vaccination does not. *See Requirement of Proof of Negative COVID-19 Test or Recovery from COVID-19 for All Air Passengers Arriving in the United States*, CDC (July 6, 2021), *available at* https://bit.ly/3yfcJDM (last visited Oct. 29, 2021).

165. Recent data from Israel suggests that individuals who receive the BioNTech Vaccine can pass the virus onto others a mere few months after receiving it, casting doubt on any claim that the vaccine prevents spread of the virus, or at least any claim that it does so to a greater extent than naturally acquired immunity.

166. Defendants offer no compelling interest in departing from the import of the science on natural immunity. There is no question that Plaintiffs possess natural immunity, given their recent antibodies screening tests and as confirmed by Dr. Sam Pappas. Pappas Decl. ¶¶10-13.

167. For similar reasons that Defendants' fail to advance a valid governmental interest in requiring that already immune employees get vaccinated, Defendants cannot show that the Federal Employee Vaccine Mandate is narrowly tailored to meet any such governmental interest.

168. That is because any interest that Defendants may have in promoting immunity does not extend to those employees who can demonstrate, through serological testing results, that they already have naturally acquired immunity.

169. This provides evidence that Defendants are trying to avoid the difficulties associated with allowing medical decisions to be made based on personal circumstances, rather than attempting to promote a legitimate public health aim.

170. The CDC concedes that so-called "breakthrough cases" exist. And in the course of doing so, the CDC actually acknowledges a lack of a public health basis for its vaccine policy:

> Vaccine breakthrough cases are expected. COVID-19 vaccines are effective and are a critical tool to bring the pandemic under control; however, no vaccine is 100% effective at preventing illness. Some fully vaccinated people will get sick, and some will even be hospitalized or die from COVID-19. *However, there is evidence that vaccination may make illness less severe for those who are vaccinated and still get sick.*

CDC, *COVID-19 Vaccine Breakthrough Case Investigation and Reporting*, *available at* https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html (last visited Oct. 29, 2021) (emphasis added). The italicized text represents an individualized benefit of vaccination, not a public health one.

171. In other words, CDC (represented in this suit by Dr. Rochelle Walensky, the CDC's Director and member of the White House COVID-19 Response Team) does not pretend that the Federal Employee Vaccine Mandate is truly about protecting others, since naturally acquired immunity also prevents hospitalizations, severe disease, and death. And this point certainly drives

home the arbitrary nature of the position that robust, naturally acquired immunity should not be recognized, while only the more limited immunity acquired through vaccination should be. Thus, this mandate infringes on Plaintiffs' bodily autonomy with no public health justification.

172. Indeed, the refusal to recognize naturally acquired immunity is a phenomenon unique to this pandemic. Even the United States military exempts individuals who can demonstrate naturally acquired immunity to the disease in question from the requisite vaccine mandate. *See* "Immunization Exception Guidance," *The Official Website of the Military Health System*, *available at* https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services/Exemption-Guidance (last visited Oct. 29, 2021).

173. In sum, Defendants' implicit justifications for the Federal Employee Vaccine Mandate are both speculative and logically incoherent.

174. Another reason the Federal Employee Vaccine Mandate lacks any constitutional validity is that many of the vaccines that the Task Force accepts, such as the Janssen, Sinovac, and Sinopharm vaccines are much less effective when it comes to preventing infection than natural immunity. Plaintiffs are, therefore, significantly less likely to contract or spread the virus than their colleagues who have been immunized with these inferior vaccines. Yet Plaintiffs are subject to termination while their similarly situated colleagues are not.

175. By failing to tailor the Federal Employee Vaccine Mandate to only those employees who lack immunity of any kind (or of a sufficient level), Defendants force employees like Plaintiffs (and those similarly situated), who have naturally acquired immunity, to choose between their health, their personal autonomy and their careers.

176. Plaintiffs have suffered and will continue to suffer damage from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate

Plaintiffs for the deprivation of their constitutional rights. They will suffer irreparable harm unless this Court enjoins Defendants from enforcing the Federal Employees Vaccine Mandate against employees with natural immunity. Once an employee is forced to take the vaccine, there is no way to unring that bell. Any harm is therefore irreparable. *See Fraternal Order of Police Chicago Lodge No. 7 v. City of Chicago*, Case No, 2021 CH 5276 (Ill. Cir. Ct. Nov. 1, 2021) ("If every union member complied and was vaccinated by December 31 (or otherwise exempt), they would have no grievance to pursue and there would be no remedy an arbitrator could aware. An aware of back pay or reinstatement cannot undo a vaccine. Nothing can.").

177. Plaintiffs are entitled to a judgment declaring that the Federal Employees Vaccine Mandate violates their constitutional rights to refuse medical treatment and an injunction restraining Defendants' enforcement of this mandate.

COUNT II: VIOLATION OF THE UNCONSTITUTIONAL CONDITIONS DOCTRINE AND THE FIFTH AMENDMENT'S RIGHT TO DUE PROCESS OF LAW

178. Plaintiffs reallege and incorporate by reference the foregoing allegations as if fully set forth herein.

179. Unconstitutional conditions case law often references the existence of varying degrees of coercion. According to that body of law, Defendants cannot impair Plaintiffs' right to refuse medical care through subtle forms of coercion any more than it could through an explicit mandate. *See, e.g., Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595 (2013) ("[U]nconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them"); *Memorial Hosp. v. Maricopa Cty.*, 415 U.S. 250 (1974) (finding that state residency requirement impinged on the

constitutionally guaranteed right to interstate travel, while lacking a compelling state interest, and thus was unconstitutional).

180. The Due Process Clause of the Fifth Amendment provides: "No person shall be … deprived of life, liberty, or property, without due process of law … ." U.S. Const., amend. V.

181. Plaintiffs possess both a liberty interest in maintaining their bodily integrity and a property interest in their careers, as well as statutory and constitutional interests in the right to refuse EUA vaccines.

182. It is less appreciated than it ought to be in legal circles that unconstitutional conditions claims do not need to establish that a challenged government policy amounts to coercion. Instead, it is sufficient that the state policy burdens a constitutional right by imposing undue pressure on an otherwise voluntary choice with a nexus to the exercise of a constitutional right.

183. In other words, the presence of some remaining voluntarism after new conditions are imposed on the exercise of a constitutional right does not stand as a barrier to mounting a successful unconstitutional conditions claim. This is especially true when a government actor couples an unconstitutional condition with a procedural system stacked against the right-holder.

184. For example, in *Speiser v. Randall*, 357 U.S. 513 (1958), the Court invalidated a loyalty oath imposed as a condition for veterans to obtain a state property tax exemption, even though (a) California citizens were not required to own real property, of course; (b) California veterans could freely opt not to seek the exemption and simply pay the unadorned tax; and

(c) California was not even obligated to provide veterans with the exemption but rather the exemption was a mere privilege.

185. The *Speiser* Court deemed the oath condition unconstitutional in part because the burden to establish qualification for the exemption was placed on applicants. *See id.* at 522. The question the Supreme Court saw itself deciding was "whether this allocation of the burden of proof, on an issue concerning freedom of speech, falls short of the requirements of due process." *Id.* at 523.

186. The Court addressed this question by stating the guiding principle that

> Where one party has at stake an interest of transcending value—as a criminal defendant his liberty—this margin of error is reduced as to him by the process of placing on the other party the burden of producing a sufficiency of proof in the first instance …. [But] Due process commands that no man shall lose his liberty unless the Government has borne the burden of producing the evidence and convincing the factfinder of his guilt.

Id. at 525-26.

187. Here, the analogue of the criminal defendant rights of "transcending value" referenced in *Speiser* are the liberty rights of all persons to be free from unconsented-to bodily intrusions and medical interventions. This means that unconstitutional conditions doctrine and due process rights *combine* to invalidate the Federal Employee Vaccine Mandate. That result occurs because Defendants have not and cannot show that forcing Plaintiffs and those similarly situated to take the vaccine reduces any risk that they will become infected with and spread the virus to other federal personnel or to the citizenry.

188. Similar to the California law in *Speiser* "creat[ing] the danger that … legitimate utterance will be penalized," 357 U.S. at 526, the process Defendants have established in relation

to taking COVID-19 vaccines poses dangers to Plaintiffs' health (and thus to their liberty interest) as well as threatening them with penalties if they do not comply.

189. Indeed, more so than in *Speiser*, the factual issues involved in this case are complex. "How can a claimant … possibly sustain the burden of proving the negative of these complex factual elements? In practical operation, therefore, this procedural device must necessarily produce a result which the State could not command directly." *Id.* There is perhaps no better encapsulation than the preceding sentence by the Supreme Court of how unconstitutional conditions doctrine and procedural due process can and do intersect and reinforce one another. *See also id.* at 529 ("The State clearly has no such compelling interest at stake as to justify a short-cut procedure which must inevitably result in suppressing protected speech."). Defendants similarly possess no compelling interest that could justify its defective Federal Employees Vaccine Mandate that will inevitably result in at least some unwarranted medical intrusions into the bodies of members of the community of federal employees and, importantly, harm to many of the plaintiffs from getting vaccinated.

190. For these reasons, Defendants cannot by means of their Federal Employee Vaccine Mandate effectively flip the burden of proof and require Plaintiffs and others similarly situated to prove that it is safe for them to perform their respective jobs while unvaccinated. And setting up such a process, which is what the Federal Employees Vaccine Mandate does, thereby represents a concurrent *procedural due process of law violation and* an unconstitutional condition burdening Plaintiffs' liberty interests to be free of unwanted medical interventions.

191. *Speiser* also rests on the mismatch between the loyalty oath California required and the grant of a property tax exemption to veterans. "[T]he State is powerless to erase the service

which the veteran has rendered his country; though he be denied a tax exemption, he remains a veteran." *Id.* at 528.

192. In this situation, there is an equally jarring logical incongruity. Defendants' Federal Employee Vaccine Mandate is relatively terse. It offers no justifications for why the penalties and other restrictions it establishes are appropriate and tailored to members of the federal employee community who have acquired robust natural immunity. And the rationales offered by Task Force participants are both logically incoherent and overlook key problems. Whatever Defendants are trying to decree through its unconstitutional-conditions sleight of hand, Plaintiffs remains federal employees with natural immunity as a matter of pre- or concurrent Federal Employee Vaccine Mandate fact (just as the *Speiser* veterans remained veterans as a matter of pre-tax-law fact), and the existence of such immunity fully serves the supposed purposes of the public-health protection that Defendants say that they are pursuing.

193. The proportionality of the Federal Employees Vaccine Mandate is also deficient because it does not seek to assess the current antibody levels of its targets, something that it is now feasible for medical science to test.[17] This means that many federal workers who are vaccinated but for some reason fail to develop sufficient antibody levels are treated more favorably than the naturally immune who in fact possess more robust immunity levels.

194. The Federal Employee Vaccine Mandate is not a mere initial presumption that vaccination is superior to natural immunity (a contention that would have to be borne out by the

[17] Such antibody testing was not possible more than a century ago when *Jacobson v. Massachusetts* was decided, as diagnostic antibody testing was not invented until the 1970's. 197 U.S. 11 (1905) (upholding a city regulation fining individuals $5 if they refused to take Smallpox vaccine). *See The History of ELISA from Creation to COVID-19 Research*, MOLECULAR DEVICES, *available at* https://www.moleculardevices.com/lab-notes/microplate-readers/the-history-of-elisa (last visited Oct. 29, 2021).

science in any event or else Defendants had no business adopting their Federal Employee Vaccine Mandate) that Plaintiffs can try to overcome.

195. The Federal Employee Vaccine Mandate is, in essence, *a conclusive presumption* (and thus a procedural due process of law violation) that vaccination is required (even as to vaccines of far-lesser efficacy), unless the risks of the vaccine to a particular recipient warrant a special exception.

196. But Plaintiffs and others with naturally acquired immunity possess more robust immunity than those who took one or more of the various inferior vaccines that Defendants accept and equivalent or greater levels to those who took the mRNA vaccines approved by the FDA.

197. Defendants have, in essence, deemed all vaccines to be equally protective in the fictitious presumption they have established. There is no scientific basis for the false suppositions that Defendants have built into the Federal Employee Vaccine Mandate.

198. For the foregoing reasons, the *de facto* presumptions the Federal Employees Vaccine Mandate establishes become another part of Defendants procedural due process of law violations that run afoul of unconstitutional conditions doctrine. In short, by allocating burden-of-proof-responsibility to those with natural immunity like Plaintiffs, coupled with Defendants' stacking the process deck with presumptions that Plaintiffs have shown are scientifically unwarranted, Defendants contravene the Due Process Clause. *See Perry v. Sinderman*, 408 U.S. 592, 597 (1972) (holding that the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"); *Wieman v. Updegraff*, 344 U.S. 183, 192 (1952) ("We need not pause to consider whether an abstract right to public employment exists. It is sufficient to say that constitutional protection does extend to the public servant whose exclusion pursuant to a statute is patently arbitrary or discriminatory.").

COUNT III: THE FEDERAL EMPLOYEE VACCINE MANDATE VIOLATES THE EQUAL PROTECTION COMPONENT OF THE DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT

199. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

200. The equal protection component of the Due Process Clause of the Fifth Amendment guarantees Plaintiffs' rights to equal protection under the law. *See United States Dep't of Agric. v. Moreno*, 413 U.S. 528 (1973) ("While the Fifth Amendment contains no equal protection clause, it does forbid discrimination and is so unjustifiable as to be violative of due process.") (cleaned up). *Moreno* invalidated on equal protection grounds the congressional Food Stamp Act's rendering ineligible for that form of public benefit any household containing an individual unrelated to any other member of the household.

201. The Federal Employee Vaccine Mandate treats unequally the two forms of immunity to COVID-19, irrationally favoring vaccine-based immunity while irrationally disfavoring natural immunity.

202. There is no rational basis in the scientific record for treating vaccine-based immunity as always and in everyone superior to natural immunity. *See City of Cleburne v. Cleburne Living Ctr., Inc.*, 472 U.S. 432 (1985). The science is to the contrary, marking out natural immunity as generally superior to vaccine-induced immunity. Hence, it is unconstitutional for the Federal Employee Vaccine Mandate to wholly ignore the issue of natural immunity and/or to refuse to forebear employment discipline where natural immunity exists.

203. Equal protection problems are compounded because individuals with naturally acquired immunity are at a disadvantage when it comes to vaccination, since immunization poses a greater risk of harm to them than to those who are unvaccinated and have not acquired immunity

naturally. Thus, through no fault of their own, Plaintiffs are in a position where they have to expose themselves to a heightened risk of adverse side effects.

204. Equal protection problems are also compounded because the Federal Employees Vaccine Mandate effectively creates, at least prior to the separation of disciplined workers from federal service, two classes of workers—those allowed relative freedom to continue to work and those denied such freedoms and saddled with employment fetters and discipline, without any rational justification.

205. The Federal Employee Vaccine Mandate, on its face, improperly grants exemptions for some medical conditions while denying natural immunity-based exemptions.

206. For all of these reasons, the Federal Employee Vaccine Mandate on its face is causing and will continue to cause irreparable harm and undue hardship to Plaintiffs.

COUNT IV: THE FEDERAL EMPLOYEES VACCINE MANDATE IS CONTRARY TO FEDERAL STATUTORY LAW

207. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

A. The EUA Statute Renders Defendants' Federal Employee Vaccine Mandate Invalid

208. Defendants' Federal Employee Vaccine Mandate requires Plaintiffs and others similarly situated to receive a vaccine in order to continue working in federal employment without regard to their natural immunity or the advice of their doctors.

209. Plaintiffs and others must also divulge personal medical information to the satisfaction of the Task Force and are threatened with disciplinary action if they decline to comply with these arbitrary mandates.

210. The Federal Employee Vaccine Mandate thus coerces or, at the very least, unduly pressures, Plaintiffs and others like them into getting vaccines that FDA approved only for emergency use.

211. The EUA statute mandates informed and voluntary consent. *See John Doe No. 1 v. Rumsfeld*, No. Civ. A. 03-707(EGS), 2005 WL 1124589, *1 (D.D.C. Apr. 6, 2005) (allowing use of anthrax vaccine pursuant to EUA "on a *voluntary* basis"). *See also* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

212. It expressly states that recipients of products approved for use under it be informed of the "option to accept *or refuse* administration" (emphasis added) and of the "significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown." *Id.*

213. Since the Federal Employee Vaccine Mandate coerces Plaintiffs by making enjoyment of their constitutionally and statutorily protected consent rights contingent upon receiving an experimental vaccine, it cannot be reconciled with the letter or spirit of the EUA statute. *See* 21 U.S.C. § 360bbb-3.

214. The conflict between the Federal Employee Vaccine Mandate and the EUA statute is particularly stark given that the statute's informed consent language requires that recipients be given the "option to refuse" the EUA product. That is at odds with this mandate effectively forcing Plaintiffs to sustain significant injury to their careers if they refuse the vaccine.

B. The FDA's Approval of the Comirnaty Vaccine Does Not Save the Task Force's Federal Employee Vaccine Mandate from Invalidity

215. The other defense that we anticipate Defendants mounting is premised on the recent FDA approval of the Comirnaty Vaccine.

216. That the Comirnaty Vaccine has received full FDA approval does not foreclose the argument presented in this count that a federal statute trumps EO 14,043 and the Task Force Guidance issued under the EO's umbrella. That is because this approval does not extend to the BioNTech Vaccine, which is actually available. Indeed, even Pfizer acknowledges that the two vaccines are "legally distinct."

217. The two Pfizer vaccines are legally distinct and include differences. For example, the two vaccines have different number of ingredients: Comirnaty has eleven (11) ingredients while Pfizer-BioNTech has just ten (10) ingredients. FDA, Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) (Aug. 23, 2021), *available at* https://www.fda.gov/media/151733/download (last viewed Nov. 1, 2021).

218. The approval announcement posted on the FDA's website reads, "On August 23, 2021, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the PfizerBioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older." *Id.*

219. While Pfizer's Comirnaty approval letter states that its two vaccines share the same formulation, the FDA concedes that "the products are legally distinct with certain differences . . ." *Id.* (emphasis added).

220. To date, no entity has revealed, nor have Plaintiffs been able to obtain, any evidence indicating what those "certain differences" may be. Despite this, the FDA asserts that the two formulations can be used interchangeably.

221. For example, in the FDA's fact sheet for recipients and caregivers, for example, it reads, "The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA authorized

Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series." *Id.*

222. In a press release announcing Pfizer's collaboration with Brazil's Eurofarma to manufacture COVID-19 vaccine doses, Pfizer wrote, "COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech" and "PfizerBioNTech COVID-19 Vaccine has received EUA from FDA." The press release continued, stating, "This emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) . . ." *Pfizer, Pfizer and BioNTech Announce Collaboration with Brazil's Eurofarma to Manufacture COVID-19 Vaccine Doses for Latin America* (Aug. 26, 2021), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-brazils (last visited Nov. 3, 2021).

223. Then, in a September 6, 2021, press release announcing a submittal to a request by the European Medicines Agency (EMA) to update its Conditional Marketing Authorization (CMA) for a booster dose, BioNTech–Pfizer's co-partner in the production of the Pfizer-BioNTech COVID-19 vaccine–clearly states, "The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by [FDA]" but has been authorized under an EUA. Press Release, *Pfizer and BioNTech Submit a Variation to EMA with the Data in Support of a Booster Dose of COMIRNATY®, BIONTECH* (Sept. 6, 2021), *available at* https://investors.biontech.de/node/10581/pdf (last visited Nov. 3, 2021).

224. The claim that the two vaccines are interchangeable comes from a Guidance document, which does not carry force of law. *See Christensen v. Harris County*, 529 U.S. 576, 587-88 (2000) ("Interpretations such as those in opinion letters—like interpretations contained in

policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference."); *Appalachian Power v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (guidance documents that agencies treat as *de facto* law are void because they did not run the notice-and-comment gauntlet) (setting aside an agency guidance document in its entirety); *see also Texas v. EEOC*, 933 F.3d 433, 443 (5th Cir. 2019) (applying *Appalachian Power*'s analysis to an EEOC guidance document the court went on to invalidate); *Gate Guard Servs. L.P. v. Solis*, Civ. A. No. V-10-91, 2011 SL 2784447, *5 (S.D. Tex. July 12, 2011) (following *Appalachian Power* and rejecting a Department of Labor defense to a challenge to statements by its regulators at "final conferences" were mere;y informal and preliminary verbal opinions).

225. The FDA cannot convert a legally distinct product that is available (the BioNTech vaccine) into a fully approved vaccine (Comirnaty) that is not yet widely available. The FDA, via a mere guidance document, is improperly trying to establish equivalence between what are two legally distinct vaccines. That is improper as a general matter of administrative law. It is yet more improper since it is a maneuver conducted to override federal statutory rights to informed medical consent.

226. Defendants cannot be permitted to rely on mere FDA-issued guidance documents, especially not where doing so would vitiate clear statutory rights.

227. Indeed, even the government has acknowledged that no particular individual can be guaranteed access to a specific version of the vaccines at any given time. "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." (cite to task force guidance)

228. Moreover, specifically referring to the Comirnaty Vaccine, Pfizer has admitted that there "is not sufficient approved vaccine available for distribution to this population in its entirety at the time of the reissuance of this EUA."

229. Since the Comirnaty Vaccine, being the only FDA-approved vaccine, is not widely available, and certainly is not available to all members of the population, nor is the legally distinct BioNTech, the EUA statute's sphere of operation continues to apply to override the Federal Employee Vaccine Mandate.

230. Indeed, the Task Force Guidance warns that meeting the deadlines rests exclusively on the shoulders of the employees, availability problems being no excuse at that point: "Depending on employees' locations, they may not have all types of vaccines available to them. Agencies should encourage employees to plan ahead and allow enough time to receive all required vaccine doses before the November 8 deadline to have their second shot." Thus, *assuming arguendo* the Comirnaty was the same as BioNTech, no federal employee can be guaranteed access to the latter, meaning that some will effectively be forced to take an EUA approved vaccine.

231. Furthermore, the Federal Employee Vaccine Mandate accepts many vaccines that have not received full FDA approval.

COUNT V: THE FEDERAL EMPLOYEE VACCINE MANDATE IS ARBITRARY & CAPRICIOUS WITHIN THE MEANING OF THE ADMINISTRATIVE PROCEDURE ACT ("APA")

232. Plaintiffs reallege and incorporate by reference all the foregoing allegations as though fully set forth herein.

233. The Federal Employee Vaccine Mandate is poorly or defectively explained in numerous respects. Most importantly, neither EO 14,043 nor the Task Force Guidance document offers any explanation as to why naturally acquired immunity is not a permissible ground for federal employees to refuse to take a COVID-19 vaccine in order to avoid discipline and keep their

jobs. Especially where naturally acquired immunity exists for individuals at a level equivalent to or superior to the least effective approved COVID-19 vaccine (*i.e.*, one of the mandate's approved foreign vaccines), this missing explanation is fatal to the policy of the Federal Employee Vaccine Mandate.

234. It is also arbitrary and capricious for an agency to ignore an important aspect of the problem. *See Motor Vehicle Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious if the agency (i) "has relied on factors which Congress has not intended it to consider"; (ii) "entirely failed to consider an important aspect of the problem"; (iii) "offered an explanation for its decision that runs counter to the evidence before the agency"; or (iv) "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

235. No less than current Pfizer Board Member and former FDA Commissioner Dr. Scott Gottlieb[18] has acknowledged that natural immunity is an important part of the problems related to fashioning a proper public policy to address COVID-19. "It's fair to conclude …" "[t]he balance of the evidence demonstrates that natural immunity confers a durable protection." Gottlieb Interview, Squawkbox CNBC (Aug. 30, 2021) *available at* https://twitter.com/i/status/1432321613467357187 (last visited Oct. 29, 2021) (on the video, Dr. Gottlieb calls natural immunity not just "durable" but "robust"). Most importantly, Dr. Gottlieb told CNBC that it cannot be disputed that officials "should start assimilating [natural immunity] into our policy discussions." *Id.* Yet there is no evidence that the Task Force assimilated naturally acquired immunity into the policy ordered in the Federal Employee Vaccine Mandate. Accordingly, the

[18] Dr. Gottlieb received his medical degree at the Icahn School of Medicine at Mount Sinai and he completed his residency at the Mount Sinai Hospital.

Federal Employee Vaccine Mandate is arbitrary and capricious within the meaning of the APA, 5 U.S.C. § 706(2)(A).

236. Additional arbitrariness issues abound. For example, there is no indication that Congress intended to allow a policy like the Federal Employee Vaccine Mandate to authorize compliance via foreign vaccines that have not been approved by duly appointed regulatory authorities at the FDA. Indeed, it is *inherently* arbitrary and capricious to include on a menu of coercive vaccine options vaccines not approved for use in the United States. In addition, it is arbitrary and capricious to set these aggressive deadlines for compliance with the Federal Employee Vaccine Mandate knowing fully that they would precede the issuance of either regulations and other agency-specific policies precisely so as (a) to coerce federal employees into rushing to get a COVID-19 vaccine before such regulations or more detailed guidance providing true fair notice could be put in place; and (b) to frustrate the ability of federal employees wanting to seek judicial review to avoid taking a vaccine.

237. Furthermore, the fact that there is no ability, under any set of conditions, to apply for an exemption to the mandate even if one can demonstrate the most robust and durable natural immunity levels reveals that the Federal Employee Vaccine Mandate rests on reasoning so implausible that it cannot be ascribed to a valid difference in expert opinion or to special agency expertise.

238. Administrative ease, the most generous explanation for the mandate's failure to recognize naturally acquired immunity, should not override an individual's right to decline an unnecessary medical intervention.

239. The APA, 5 U.S.C. § 706(2)(B), also provides a cause of action carrying Counts I, II, and III pleaded above because those counts are designed to seek enforcement of the

Constitution. And 5 U.S.C. § 706(2)(A)&(C) supports Count IV, which seeks invalidation of the Federal Employee Vaccine Mandate because it is not "otherwise in accordance with law" and because it is "in excess of statutory jurisdiction, authority, or limitations, [and] short of statutory right."

ADDITIONAL OVERARCHING LEGAL CLAIMS

240. Plaintiffs have suffered and will continue to suffer harm from Defendants' conduct. There is no adequate remedy at law, as there are no damages that could compensate Plaintiffs or all Class Members for the deprivation of their constitutional and statutory rights, nor for the consequences of being forced to take a vaccine. Plaintiffs will suffer irreparable harm unless this Court enjoins Defendants from enforcing the Federal Employee Vaccine mandate.

241. The Administrative Procedure Act permits the actions of Defendants to be reviewed. *See* 5 U.S.C. §§ 702 through 706.

a. Specifically, review can be sought here because Plaintiffs are suffering legal injury because of agency action that adversely affects and aggrieves them. *See* 5 U.S.C. § 702.

b. The form of proceeding here encompasses actions for declaratory judgment and for prohibitory or mandatory injunctions. *See* 5 U.S.C. § 703.

c. The Federal Employee Vaccine Mandate is final agency action for which there is no adequate remedy in a court. The "entire Guidance, from beginning to end . . . reads like a ukase. It commands, it requires, it orders, it dictates." *Appalachian Power v. EPA*, 208 F.3d at 1023 ("The short of the matter is that the Guidance, insofar as relevant here, is final agency action, reflecting a settled agency position which has legal consequences …."). Indeed, this mandate has (i) already coerced many federal employees into taking a COVID-19 vaccine contrary to their wishes; and (ii) will continue to coerce federal employees to do so unless it is halted.

Finally, (iii) the deadlines set in this mandate come due in the very near term, with suspensions being imposed in less than one month and separation from federal service being imposed in just over one month. *See* 5 U.S.C. § U.S.C. § 704.

d. This suit is similarly ripe because the question it presents is predominantly legal—is the Federal Employee Vaccine Mandate on its face unconstitutional and/or barred by the EUA statute?—and because Plaintiffs would suffer hardship if they are disciplined or terminated from federal employment.

e. This Court possesses the power to postpone the effective date of the Task Force's actions taken under the rubric of the Federal Employee Vaccine Mandate or to preserve the *status quo* and rights of Plaintiffs pending conclusion of judicial review. *See* 5 U.S.C. § 705.

f. As noted above, this Court can decide all questions of law, compelling agency action unlawfully withheld or unreasonably delayed, holding unlawful and setting aside agency actions, findings and conclusions found to be (i) arbitrary and capricious, (ii) unconstitutional, (iii) in excess of statutory power; and (iv) without observance of procedure required by law.

g. Likewise, Plaintiff is entitled to injunctive relief pursuant to *Larson*'s nonstatutory equitable right of action. *See, e.g., Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1329 (D.C. Cir. 1996) (invalidating Executive Order 12,954 through the device of a *Larson* nonstatutory review action, meaning that "sovereign immunity does not bar [such] a suit," and specifically holding that a federal statute overrode that Executive Order).

h. In sum, Plaintiffs are entitled to a judgment declaring that the Federal Employee Vaccine Mandate is *ultra vires* under both the Constitution and under the EUA statute,

along with an injunction restraining Defendants' enforcement of this mandate, since it is inconsistent with superior federal law.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that the Court find the Defendants have committed the violations alleged and described above, and issue in response the following:

A. A declaratory judgment that the Federal Employee Vaccine Mandate infringes upon Plaintiffs' constitutionally protected rights to protect their bodily integrity and autonomy and to refuse unnecessary medical treatment.

B. A declaratory judgment that the Federal Employee Vaccine Mandate represents an unconstitutional condition, especially in light of a set of explicit and implicit procedures that violate the Due Process Clause of the Fifth Amendment.

C. A declaratory judgment that the Federal Employee Vaccine Mandate represents a violation of the equal protection rights of Plaintiffs.

D. A declaratory judgment that the Federal Employee Vaccine Mandate is invalid under the EUA statute because the Task Force Guidance fails to provide for the informed-consent right to refuse a COVID-19 vaccine;

E. A declaratory judgment holding that the Federal Employee Vaccine Mandate is arbitrary and capricious;

F. Temporary, preliminary and permanent injunctive relief restraining and enjoining Defendants, their agents, servants, employees, attorneys, and all persons in active concert or participation with them (*see* Fed. R. Civ. P. 65(d)(2)), and each of them, from enforcing coercive or otherwise pressuring policies or conditions to get a COVID-19 vaccine similar to those in the Federal Employee Vaccine Mandate that act to compel or try to exert leverage on federal employee Class Members with natural immunity; AND

G. Plaintiffs seek nominal damages of $1.

JURY DEMAND

Plaintiff herein demands a trial by jury of any triable issues in the present matter.

November 5, 2021

Respectfully submitted,

Respectfully submitted,

/s/ John J. Vecchione

John J. Vecchione
Senior Litigation Counsel
Virginia Bar # 73828
John.Vecchione@ncla.legal
Motion to Be Admitted as Attorney-in-Char
Pending

/s/

Jenin Younes*
Litigation Counsel
New York Bar # 5020847
Jenin.Younes@ncla.legal
Pro Hac Vice Admission Forthcoming
* Admitted only in New York. DC practi
limited to matters and proceedings befc
United States courts and agencies. Practici
under members of the District of Columb
Bar.

/s/

Harriet Hageman
Senior Litigation Counsel
Wyoming Bar # 5-2656
Harriet.Hageman@ncla.legal
Pro Hac Vice Admission Forthcoming

NEW CIVIL LIBERTIES ALLIANCE
1225 19th Street NW, Suite 450
Washington, DC 20036

Telephone: (202) 869-5210
Facsimile: (202) 869-5238

/s/ *Robert Henneke*
ROBERT HENNEKE
Texas Bar # 24046058
TEXAS PUBLIC POLICY FOUNDATION
901 Congress Avenue
Austin, TX 78701
Telephone: (512) 472-2700
Facsimile: (512) 472-2728
rhenneke@texaspolicy.com

Attorneys for Plaintiffs